UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

THE UNITED STATES OF AMERICA,
THE STATE OF NEW YORK,
THE STATE OF NEW JERSEY,
THE STATE OF CALIFORNIA,
THE STATE OF COLORADO,
THE STATE OF CONNECTICUT,
THE STATE OF FLORIDA,
THE STATE OF GEORGIA,
THE STATE OF ILLINOIS,
THE STATE OF INDIANA,
THE STATE OF LOUISIANA,
THE STATE OF MARYLAND,
THE COM. OF MASSACHUSETTS,
THE STATE OF MICHIGAN,
THE STATE OF NEVADA,
THE STATE OF NORTH CAROLINA,
THE STATE OF RHODE ISLAND,
THE STATE OF TENNESSEE,
THE STATE OF TEXAS,
THE COM. OF VIRGINIA,
ex rel. JOHN PEPE, M.D., and RICHARD SHERMAN, M.D.,

Plaintiffs,

vs.

FRESENIUS SE & Co. KGaA, FRESENIUS MEDICAL CARE AG & Co. KGaA, FRESENIUS MEDICAL CARE HOLDINGS, INC., FRESENIUS VASCULAR CARE, INC., and GREGG MILLER,

Defendants.

Civil Action No. 14-cv-3505
(Block, J.)
(Go, M.J.)

FILED IN CAMERA AND UNDER SEAL IN ACCORDANCE WITH THE FALSE CLAIMS ACT 31 U.S.C. § 3730(b)(2)

DO NOT PLACE IN PRESS BOX

DO NOT ENTER ON PACER

JURY TRIAL DEMANDED

FOURTH AMENDED COMPLAINT

I. NATURE OF THE ACTION

1. Plaintiff Relators Dr. John Pepe and Dr. Richard Sherman ("Relators") bring this False Claims Act ("FCA") action against Fresenius SE & Co. KGaA, Fresenius Medical Care AG & Co. KGaA, Fresenius Medical Care Holdings, Inc., Fresenius Vascular Care, Inc., and Gregg Miller (collectively, "Defendants") to recover hundreds of millions of dollars that Defendants have caused the federal health care programs, including Medicare, Medicaid, TRICARE, and the VA Program, and the State of New York, the State of New Jersey, the State of California, the State of Colorado, the State of Connecticut, the State of Florida, the State of Georgia, the State of Illinois, the State of Indiana, the State of Louisiana, the State of Maryland, the Commonwealth of Massachusetts, the State of Michigan, the State of Nevada, the State of North Carolina, the State of Rhode Island, the State of Tennessee, the State of Texas, and the Commonwealth of Virginia (collectively, the "Plaintiff States") through their Medicaid programs, to pay for End-Stage Renal Disease ("ESRD") related treatments that were not medically reasonable and necessary, that were not referred by a treating physician, that were not covered under applicable law, and that exposed patients to undue and unnecessary risks. This action also includes claims under the California Insurance Frauds Protection Act ("IFPA") to recover damages and other applicable financial penalties for Defendants' conduct that similarly harmed commercial insurance companies.

2. The U.S. Government is the country's largest payer of health care treatment for individuals with ESRD. Through Medicare, the Government pays over $34 billion a year for nearly half a million patients. In order to provide this health coverage in the most effective way possible, the Government has spent decades refining the Medicare ESRD payment system to pay health care providers for legitimate treatments for ESRD while excluding coverage for wasteful

and potentially harmful procedures that are not "reasonable and necessary" for the clinical treatment of patients.

3. For those ESRD patients that are eligible for Medicaid, the Medicaid programs of the Plaintiff States will pay Medicare copayments and/or deductibles for ESRD services. Medicaid programs also provide ESRD coverage for the first 90 days of a patient's treatment, which is not covered by Medicare.

4. Since at least October 2011 and continuing to this day, Fresenius, one of the country's largest health care organizations, has engaged in a scheme to undermine the Government's efforts to provide effective ESRD coverage and to fraudulently obtain hundreds of millions of dollars of Government funds by performing unnecessary "fistulagrams" and related procedures on ESRD patients without their treating physicians' consent, falsifying patient records in connection therewith, and then submitting false claims for reimbursement, all at the expense of the American taxpayer.

5. This illegal scheme is conducted as follows: As part of standard dialysis treatment (which generally takes place three times weekly), the patient's vascular system of veins and arteries is monitored by the dialysis provider using various modalities described in more detail herein. When these modalities indicate the presence of an obstruction in the patient's vascular access that is preventing the dialysis treatment from effectively removing toxins from the blood, the treating physician may refer the patient to a Fresenius Vascular Care facility to perform a one-time diagnostic procedure, called a fistulagram, and if appropriate, to then restore the patient's vascular access to a level sufficient to allow dialysis to be effective. Once Defendants have a patient in their grasp, however, they proceed to schedule and perform numerous unnecessary fistulagrams and related procedures over the course of months or years,

ignoring the true medical needs of the patient and instead viewing her person only as a means through which Defendants can fraudulently obtain Medicare and Medicaid payments from the Government. And indeed, Defendants have targeted not only Government dollars but those of commercial insurance companies as well.

6. A fistulagram involves the penetration of a patient's skin and blood vessels with a needle, the insertion of a catheter (via a guide wire) into those blood vessels, the injection of dye into the catheter and the X-ray imaging of those vessels. Other commonly performed, yet often entirely unnecessary, procedures include angioplasties – the insertion of a catheter into a patient's blood vessel which contains a small balloon that is inflated to stretch out and expand the vessel. Defendants routinely perform these procedures when there is no clinical indication that a patient's dialysis is impaired in any way. In many cases the patient had undergone successful dialysis just one day prior to their visit at Defendants' facility and moreover, their vascular access had been regularly monitored while receiving dialysis and no indications of impairment were detected. Defendants subject patients to these procedures which commonly have little or no value to the patient and present significant health risks, and are accordingly not covered by Medicare or Medicaid.

7. To enable and disguise their fraudulent scheme, Defendants falsify patient records to (1) indicate that a patient's treating physician – and not, as is the case, Fresenius's own employees – had referred a patient for multiple procedures over many months; and (2) justify these serial procedures, by routinely relying on the purported presence of one of several "soft" indicators of impaired vascular access, such as that a patient's vein was observed to be "pulsating" at the time of the "exam." Furthermore, without notifying or seeking input from the

patient's treating physician, Defendants routinely schedule another "follow-up" visit often for an invented reason solely to inflate their revenue.

8. To induce patients, many of whom are disadvantaged minorities, elderly, or low-income individuals, to re-appear for these uncomfortable and time-consuming procedures, Defendants provide them with free meals and even limousine transportation to and from Defendants' facilities, in direction violation of the federal and New York State Anti-Kickback Statutes and False Claims Acts.

9. Relators' professional judgment, informed by a review of patient statistics from Defendant facilities, is that this fraudulent scheme accounted for around 70% of all fistulagrams performed by Defendants. Applied to Defendants' nationwide network of vascular access facilities, and when added to fraudulently billed angioplasties and other procedures, this percentage means Defendants have unlawfully obtained hundreds of millions of dollars from the U.S. Government and the Plaintiff States over the past several years, as well as reimbursements to which they were not entitled from commercial insurance companies in violation of the IFPA.

II. JURISDICTION AND VENUE

10. This Court has jurisdiction under 31 U.S.C. § 3730 *et seq.* and 28 U.S.C. §§ 1331 and 1345. The Court may exercise personal jurisdiction over Defendants because one or more of the Defendants resides and/or transacts business in this District or committed the proscribed acts in this District. Venue lies in this District pursuant to 31 U.S.C. § 3732(a), in that many of the acts complained of took place in this District and one or more Defendant(s) are located in this District.

11. This Court has supplemental jurisdiction over the claims of the Plaintiff States pursuant to 28 U.S.C. § 1367 and 31 U.S.C. § 3732(b).

III. PARTIES

A. Plaintiffs

12. The United States of America and the Plaintiff States are the real parties in interest to the claims of this action.

13. The United States brings this action on behalf of (a) the Department of Health and Human Services and the Centers for Medicare & Medicaid Services, which administer the Medicare and Medicaid programs, (b) the Department of Defense, including its component, TRICARE, and (c) the Veterans Administration, which administers the VA Program.

14. The Plaintiff States bring this action on behalf of their respective Medicaid programs and agencies, as well as their respective state interests. The interest of the State of California with respect to violations of the IFPA is represented by the California Department of Insurance and the District Attorney of Alameda County.

15. Relator Dr. John Pepe is currently an attending physician at Richmond University Medical Center ("RUMC") and Staten Island University Hospital in New York. Dr. Pepe received his medical degree from the Medical College of Pennsylvania and is board certified in internal medicine and nephrology. Dr. Pepe has devoted his career to the care and treatment of kidney disorders. Since 1982, Dr. Pepe has served as Director of Hemodialysis, first at Bayley Seton Hospital, then St. Vincent's Hospital and currently at RUMC. He is on the Medical Advisory Board of the Kidney and Urology Foundation of America, and has previously sat on the Board of Trustees for the National Kidney Foundation of NY. Dr. Pepe currently serves as Director of the Staten Island Artificial Kidney Center and the Carol Molinaro Dialysis Center, both clinics in the Dialysis Clinic, Inc. ("DCI") network. Dr. Pepe resides in Staten Island, New York.

16. Relator Dr. Richard Sherman is a professor emeritus of medicine at Rutgers University and Medical Director of Dialysis at the Robert Wood Johnson University Hospital in New Brunswick, New Jersey. Dr. Sherman graduated from Albert Einstein College of Medicine of Yeshiva University in 1975. Dr. Sherman specializes in the field of nephrology and diagnoses and treats diseases and complications of the kidneys. Dr. Sherman was a member of the National Kidney Foundation's Dialysis Outcomes Quality Initiative ("KDOQI") Vascular Access Committee, which in 2006 issued its widely-used guidelines for fistula care and treatment. He has served as the Editor in Chief of the journal *Seminars in Dialysis* for the past three decades, and has published over 100 peer reviewed articles and book chapters in the field of dialysis. Dr. Sherman resides in Westfield, New Jersey.

17. The allegations in this Complaint are based upon information and documents Relators learned and discovered first-hand during the course of performing their professional responsibilities, from their personal interactions with Defendants' facilities, and from their discussions with individual patients who were and remain subjected to Defendants' fraudulent scheme.

B. Defendants

18. Defendant Fresenius SE & Co. KGaA ("Fresenius SE") is a global health care group with headquarters at Else-Kroner-Str. 1, 61352 Bad Homburg, Germany. It has the legal form of a German partnership limited by shares. Fresenius SE has stock that trades on the Frankfurt Stock Exchange (ticker: FRE) and American Depository Receipts that trade over-the-counter (symbol: FSNUY).

19. Fresenius SE is organized into four business segments, the largest of which is Fresenius Medical Care AG & Co. KGaA ("Fresenius Medical Care").

20. Defendant Fresenius Medical Care is a German company with the legal form of a partnership limited by shares, headquartered at Else-Kroner-Str. 1, 61346 Bad Homburg, Germany. Fresenius Medical Care's shares trade on the Frankfurt Stock Exchange (ticker: FME), and its American Depository Receipts trade on the New York Stock Exchange (ticker: FMS).

21. In 2013, Fresenius Medical Care generated total revenues of over $14 billion dollars.

22. Fresenius Medical Care's 2013 Form 20-F, filed with the Securities and Exchange Commission, describes the "de facto management control" that Fresenius SE exercises over Fresenius Medical Care:

> ***Fresenius SE owns 100% of the shares in the General Partner of our Company and is able to exercise management control of FMC-AG & Co. KGaA.***
>
> Fresenius SE owns approximately 31.3% of our outstanding ordinary shares as of February 19, 2014. Fresenius SE also owns 100% of the outstanding shares of Management AG, the General Partner of the Company. As the sole shareholder of the General Partner, Fresenius SE has the sole right to elect the supervisory board of the General Partner which, in turn, appoints the General Partner's Management Board. The Management Board of the General Partner is responsible for the management of the Company. Through its ownership of the General Partner, Fresenius SE is able to exercise de facto management control of FMC-AG & Co. KGaA, even though it owns less than a majority of our outstanding voting shares.

Fresenius Medical Care ("FMC") 2013 Form 20-F at 12.

23. Fresenius Medical Care holds itself out as the world's largest provider of dialysis products and services. Fresenius Medical Care has a global network of over 3,200 dialysis clinics in around 45 countries through which it provides services to over 270,000 patients.

24. Fresenius Medical Care divides its business segments into four regions – North America, EMEA (Europe, Middle East, Africa), Latin America, and Asia-Pacific. North America is Fresenius's most important region in terms of revenue.

25. Defendant Fresenius Medical Care Holdings, Inc. is a New York corporation that is based in Waltham, Massachusetts. Defendant Fresenius Medical Care Holdings, Inc. is a division of Fresenius Medical Care and is its North America regional headquarters. Fresenius Medical Care Holdings, Inc. does business as "Fresenius Medical Care North America."

26. Defendant Fresenius Vascular Care, Inc. ("FVC"), headquartered at 1200 West Swedesford Road, Building 3, Suite 120, Berwyn, Pennsylvania, 19312, was formed by and is a business unit of Fresenius Medical Care North America, and is one of the largest clinic networks for interventional radiology in North America. Fresenius Medical Care substantially grew the Fresenius Vascular Care business unit with the acquisition in 2011 of American Access Care Holdings for $385 million.

27. The Fresenius press release announcing the acquisition stated: "…acquiring AAC will enable [Fresenius] to achieve critical mass in its vascular access business, and [] the deal has strategic importance because of the scale, resources and operational efficiency it brings to its vascular access operations."

28. The American Access Care Holdings ("American Access Care" or "AAC") clinic network includes 28 freestanding outpatient centers providing vascular access treatment to dialysis patients in the State of New York and elsewhere in the U.S.

29. Following the acquisition, AAC clinics were absorbed operationally into the FVC chain. FVC has since added at least 15 additional vascular access clinics. According to its website, Fresenius Vascular Care presently operates 66 vascular access clinics in approximately 25 states (and Puerto Rico) throughout the United States including 12 in New York State and 4 in New Jersey.

30. Among the FVC centers is Verrazano Vascular Associates located at 2025 Richmond Avenue, Staten Island, NY 10314. On its patient records, Verrazano Vascular Associates also refers to itself as "American Access Care Physicians" and "American Access Care SI." Also among the FVC centers is "Access Care Physicians of NJ," located at 2401 Morris Avenue, Suite W112, Union, NJ 07083

31. From April 2015 through the present, defendant Gregg Miller has been the Vice President of Operations of Fresenius Vascular Care. According to FVC's website, defendant Miller is a member of FVC's "Senior Leadership." He is also a member of FVC's Medical Advisory Board which is charged with reviewing and analyzing clinical quality. Prior to being appointed V.P. of Operations, Miller served as Chief Medical Officer for FVC. And prior to Fresenius' acquisition of AAC, Miller was employed by AAC, operating AAC of Brooklyn where he performed fistulagrams and angioplasties on dialysis patients.

32. Miller is also presently the Medical Director of FVC's clinic "Dialysis Access Center-Oakland," located at 3012 Summit Street Ground Floor, D-Wing, Oakland, California 94609.

33. As of June 20, 2017, Fresenius Vascular Care changed its name to "Azura Vascular Care." The press release announcing this "strategic rebranding" stated that its vascular care centers "are supported by the resources of their experienced management team and their parent company, healthcare leader Fresenius Medical Care North America." The press release further stated that, "We want our patients, network of physicians, and communities to know that we are one integrated organization, operating daily with a common purpose." *See* https://www.azuravascularcare.com/in-the-news/fresenius-vascular-care-announces-new-name-to-reflect-companys-strategic-transformation/.

34. Fresenius Vascular Care currently operates or has operated during the relevant time period vascular access centers at the following locations:

a) Capitol City Vascular Center (now "Azura Vascular Care Capitol City"), 1501 Forest Avenue, Montgomery, AL 36106

b) Nephrology Vascular Lab, 1280 Columbiana Road, Suite 120, Birmingham, AL 35216

c) Dialysis Access Center – Oakland, 3012 Summit Street Ground Floor, D-Wing, Oakland, CA 94609

d) Pacific Interventional Vascular Access Center, 6076 Bristol Parkway, Suite 108, Culver City, CA 90230

e) Pacific VascuCare, 1660 W. 3rd Street, Los Angeles, CA 90017

f) San Diego Access Care / Southern California Vein Care, 995 Gateway Center Way, Suite 207, San Diego, CA 92102

g) Rocky Mountain Vascular Care, 2002 Lelaray Street, Suite 100, Colorado Springs, CO 80909

h) Connecticut Access Care / CT Image Guided Surgery, 501 Kings Highway East, Suite 109, Fairfield CT 06825

i) American Access Care of Florida, 6766 West Sunrise Boulevard, Suite 100, Plantation, FL 33313

j) American Access Care of Jacksonville (now "Azura Vascular Care Jacksonville"), previously located at 800 Lomax Street, Suite 100, Jacksonville, FL 32204, and presently located at 2416 Dunn Avenue, Jacksonville, FL 32218.

k) American Access Care of Miami (now "Azura Vascular Care Miami"), 9200 South Dadeland Boulevard, Suite 101, Miami, FL 33156

l) American Access Care of Orlando, 1405 South Orange Avenue, Suite 120, Orlando, FL 32806

m) Renalus Vascular Access Center – Fort Walton (now "Azura Vascular Care Renalus Fort Walton"), 925 Mar Walt Drive, Suite 2, Fort Walton Beach, FL 32547

n) Renalus Vascular Access Center – Pensacola (now "Azura Surgery Center Renalus Pensacola"), 1619 Creighton Road #2, Pensacola, FL 32504

o) South Florida Advanced Access Care, 8770 SW 144th Street, Miami, FL 33176

p) Vascular Interventions of Tampa (now "Azura Vascular Care Tampa"), 12666 Telecom Drive, Temple Terrace, FL 33637

q) Atlanta Access Care (now "Azura Vascular Care Atlanta"), 250 East Ponce De Leon Avenue, Suite 100, Decatur, GA 30030

r) Augusta Vascular Center, 630 13th Street, Suite 250, Augusta, GA 30901

s) Augusta Vascular Center – WEST, 3624 J. Dewey Gray Circle, Suite 101, Augusta, GA 30909

t) Snapfinger Vascular Access (now "Azura Vascular Care Snapfinger"), 5246 Snapfinger Park Drive, Decatur, GA 30035

u) Chicago Access Care / Makris MD, 700 Pasquinelli Drive, Westmont, IL 60559

v) Nephrology Physicians (now "Michiana Regional Vascular Center"), 250 East Day Road, Suite 300, Mishawaka, IN 46545

w) Baton Rouge Vascular Access, previously located at 7638 Picardy Avenue, Suite B, Baton Rouge, LA 70808, and presently located at 505 East Airport Avenue, Baton Rouge, LA 70806

x) American Access Care of Baltimore (now "Azura Vascular Care White Marsh"), 8140 Corporate Drive, Suite 125, Baltimore, MD 21236

y) Baltimore Vascular Care, 25 Crossroads Drive, Suite 110, Owing Mills, MD 21117

z) Montgomery Vascular Care, 2121 Medical Park Drive, Suite 5, Silver Spring, MD 20902

aa) Vascular Specialists of the North Shore, 100 Cummings Center, Suite 100 E, Beverly, MA 01915

bb) Lansing Vascular Care, 916 Mall Drive East, Suite 200, Lansing, MI 48917

cc) Lakeland Vascular Access Center, 1010 Lakeland Square EXT, Suite B, Flowood, MS 39232

dd) Northwest Vascular Care (now "Azura Vascular Care St. Louis"), 201 Dunn Road, Florissant, MO 63031

ee) Sierra Nevada Nephrology Access Center, previously located at 10085 Double R Boulevard, Suite 125, Reno, NV 89521, and presently located at 932 Ryland Street, Reno, NV 89502

ff) Nevada Kidney Disease & Hypertension Centers, 2450 Fire Mesa Street #100, Las Vegas, NV 89128

gg) Access Care Physicians of New Jersey, previously located at 2401 Morris Avenue, Suite West 112, Union, NJ 07083, and presently located at 1050 Galloping Hill Road, Suite 101, Union, NJ 07083.

hh) American Access Care of New Jersey (now "Azura Surgery Center Cherry Hill"), 207 South Kings Highway, Suite 2, Cherry Hill, NJ 08034

ii) Image Guided Surgery & Aesthetics, previously located at 2401 Morris Avenue, Suite West 111, Union, NJ 07083, and presently located at 1050 Galloping Hill Road, Suite 102, Union, NJ 07083.

jj) Verona Veins at Access Care Physicians (now "Azura Vascular Care Woodland Park"), 1225 McBride Avenue, Suite 116-117, Woodland Park, NJ 07424

kk) American Access Care of Bellmore (now "American Access Care Nassau County"), 250 Pettit Avenue, Suite 2, Bellmore, NY 11710

ll) American Access Care Brooklyn, 577 Prospect Avenue Lower Level, Brooklyn, NY 11215

mm) American Access Care of New York (now "American Access Care Manhattan"), 403 E. 91st Street, Floor 2, New York, NY 10128

nn) American Access Care Queens, 176-60 Union Turnpike #130, Suite 130, Flushing, NY 11366

oo) American Access Care Suffolk County, 32 Central Avenue, Hauppauge, NY 11788

pp) American Access Care Bronx, 1200 Waters Place N. Lobby, Suite M 115, Bronx, NY 10461

qq) Saqib Chaudhry, MD – Flushing, 176-60 Union Turnpike Utopia Center, Suite 145, Flushing, NY 11366

rr) Saqib Chaudhry, MD – Roslyn, 1044 Northern Boulevard, Suite 302, Roslyn, NY 11676

ss) Vascular Surgeons of Central New York, 104 Union Avenue, Suite 1003, Syracuse, NY 13203

tt) Verrazano Vascular Associates at Access Care Physicians, 2025 Richmond Avenue, Suite 1LL, Staten Island, NY 10314

uu) Metrolina Access Center – Charlotte, 2711 Randolph Road, Building 400, Charlotte, NC 28207

vv) Metrolina Access Center – Concord, 425 Copperfield Boulevard NE, Concord, NC 28025

ww) Raleigh Access Center, 3031 New Bern Avenue, Suite 100, Raleigh, NC 27610

xx) Triangle Vascular Associates, 2501 Weston Parkway, Suite 201, Cary, NC 27513

yy) Vascular Care of Greenville, 511 Paladin Drive, Greenville, NC 27834

zz) Vascular Care of New Bern, 970 Newman Road, New Bern, NC 28562

aaa) Azura Vascular Care Cincinnati, 4600 Smith Road, Suite A4, Cincinnati, OH 45212

bbb) Vein & Vascular Center at American Access Care of Northeast Philadelphia (now "Azura Vascular Care Northeast Philadelphia"), 7959 Bustleton Avenue, Philadelphia, PA 19152

ccc) Vein & Vascular Access Center at American Access Care of South Philadelphia (now "Azura Vascular Care South Philadelphia"), 2412 West Passyunk Avenue, Philadelphia, PA 19145

ddd) Interventional Ambulatory Center of Puerto Rico (now "Azura Vascular Care of Puerto Rico"), Parque Industrial Amuelas, Suite 105 Carretera 584 #531, Juana Diaz, PR 00795

eee) Providence Access Care, 100 Highland Avenue, Suite 100, Providence, RI 02906

fff) Vascular Care of South Carolina, 121 Park Central Drive, Suite 100, Columbia, SC 29203

ggg) University Vascular Access Care, 6490 Mr. Moriah Road Extended, Suite 202, Memphis, TN 38115

hhh) Austin Access Care, 8620 Burnet Road, Suite 400, Austin TX 78757

iii) Bay Area Vascular Center, 8537-C Gulf Freeway, Houston, TX 77107

jjj) Dialysis Access Center – Corpus Christi, 5802 Saratoga Boulevard, Suite 306, Corpus Christi, TX 78414

kkk) Endovascular & Minimally Invasive Therapies & Interventional Radiology, 6010 McPherson Road, Suite 200, Laredo, TX 78041

lll) STAR Vascular Access Center, 301 North Frio Street, San Antonio, TX 78207

mmm) Utah Vascular and Interventional Specialists, 3702 S. State Street, Suite 111, Salt Lake City, UT 84115

nnn) American Access Care of Richmond (now "Azura Vascular Care River City"), 2235 Staples Mill Road, Suite 104, Richmond, VA 23230

ooo) HealthQare Associates, 3833 Fairfax Drive, Suite 400, Arlington, VA 22203

ppp) Virginia Beach Endovascular, 397 Little Neck Road, 3300 South Building, Suite 150, Virginia Beach, VA 23452.

35. In this Complaint, Fresenius SE, Fresenius Medical Care, Fresenius Medical Care Holdings, Inc., Fresenius Vascular Care (now d/b/a Azura Vascular Care), all related corporate parents and subsidiaries, reporting segments, business units, affiliates and centers are individually and collectively referred to, along with Gregg Miller, as "Fresenius" or "Defendants."

IV. THE FEDERAL AND STATE FALSE CLAIMS ACTS

36. The FCA provides, in pertinent part, that any person who:

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim… [or]

(G) knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government

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is liable to the United States Government [for statutory damages and such penalties as are allowed by law].

31 U.S.C. § 3729(a)(1)-(7) (2006), as amended by 31 U.S.C. § 3729(a)(1)(A)-(G) (2010).

37. The FCA further provides that "knowing" and "knowingly"

(A) mean that a person, with respect to information-

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud[.]

31 U.S.C. § 3729(b) (2006), as amended by 31 U.S.C. § 3729(b)(1) (2010).

38. An "obligation," as that term is used in 31 U.S.C. § 3729(a)(1)(G), includes "the retention of any overpayment." 31 U.S.C. § 3729(b)(3). An "overpayment" is defined as "any funds that a person retains or receives under [Medicare] or [Medicaid] to which the person, after applicable reconciliation, is not entitled." 42 U.S.C. § 1320a-7k(d)(4)(B). An overpayment must be "reported and returned" within 60 days after it was identified. 42 U.S.C. § 1320a-7k(d)(2).

39. Section 3729(a)(1) of the FCA provides that a person is liable to the United States for three times the amount of damages which the Government sustains because of the act of that person, plus civil penalties. The FCA civil penalties are $5,500 to $11,000 for violations occurring from September 29, 1999 to August 1, 2016; $10,781 to $21,563 for violations occurring from August 2, 2016 to February 3, 2017; $10,957 to $21,916 for violations occurring from February 4, 2017 to January 29, 2018; $11,181 to $22,363 for violations occurring from January 30, 2018 to June 19, 2020; and $11, 665 to 23,331 for violations occurring thereafter. *See* 28 C.F.R. §§ 85.3 & 85.5; 85 Fed. Reg. 37004 (June 19, 2020).

40. Each of the Plaintiff States has enacted a false claims statute modeled after the Federal FCA and/or covering false claims for payment with respect to Medicaid. *See* California False Claims Act (Cal. Gov't. Code §§ 12650 et seq.), Colorado Medicaid False Claims Act

(Colo. Rev. Stat. §§ 25.5-4-303.5 et seq.), Connecticut False Claims Act (Conn. Gen. Stat. §§ 4-275 et seq.), Florida False Claims Act (Fla. Stat. §§ 68.081 et seq.), the Georgia State False Medicaid Claims Act (Ga. Code §§ 49-4-168 et seq.), Illinois False Claims Act (740 Ill. Comp. Stat. 175/1 et seq.), Indiana False Claims and Whistleblower Protection Act (Ind. Code §§ 5-11-5.5-1 et seq.), Louisiana Medical Assistance Programs Integrity Law (La. Rev. Stat. §§ 46:438.1 et seq.), Maryland False Health Claims Act (Md. Code, Health-General §§ 2-601 et seq.), Massachusetts False Claims Law (Mass. Laws. ch. 12, §§ 5A et seq.), Michigan Medicaid False Claims Act (Mich. Comp. Laws §§ 400.601 et seq.), Nevada False Claims Act (Nev. Rev. Stat. §§ 357.010 et seq.), New Jersey False Claims Act (N.J. Stat. §§ 2A:32C-1 et seq.), New York False Claims Act (N.Y. State Fin. Law §§ 187 et seq.), North Carolina False Claims Act (N.C. Gen. Stat. §§ 1-605 et seq.), Rhode Island False Claims Act (R.I. Gen. Laws §§ 9-1.1-1 et seq.), Tennessee Medicaid False Claims Act (Tenn. Code §§ 71-5-181 et seq.), Texas Medicaid Fraud Prevention Act (Tex. Hum. Res. Code §§ 36.001 et seq.), and Virginia Fraud Against Taxpayers Act (Va. Code §§ 8.01-216.1 et seq.).

V. THE GOVERNMENT HEALTHCARE PROGRAMS

A. General Rules For All Medicare Coverage

41. Congress established the Medicare Program in 1965 to provide health insurance coverage for people age 65 or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 426 & 426A.

42. Medicare coverage was extended to include treatment for individuals with ESRD in 1972, and was further extended when an age requirement for ESRD coverage was removed in 1978. This legislative amendment was prompted by the increasing number of patients receiving kidney dialysis and the substantial cost of this life-saving procedure. *See* 42 U.S.C. § 426-1.

43. Medical necessity is a fundamental requirement for Medicare coverage. Medicare does not cover any expenses incurred for services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury …." 42 U.S.C. § 1395y(a)(1)(A).

44. It is the obligation of every health care provider seeking reimbursement under Medicare to assure that services it provides, "(1) will be provided economically and only when, and to the extent, medically necessary; (2) will be of a quality which meets professionally recognized standards of health care; and (3) will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing quality improvement organization in the exercise of its duties and responsibilities." 42 U.S.C. § 1320c-5(a).

45. "All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." 42 C.F.R. § 410.32.

B. Medicare Coverage Of ESRD Treatment

46. Medicare is currently the country's largest payer for ESRD health care and spends over $34 billion a year for nearly half a million patients. The average cost to Medicare for a single patient on hemodialysis is over $87,000 a year.

47. Medicare has four parts, Part A (hospital insurance), Part B (medical insurance), Part C (Medicare Advantage Plans), and Part D (prescription drugs). Certain ESRD treatments

such as kidney transplants may be covered by Part A. Many outpatient ESRD treatments are covered by Part B.

48. During the past four-plus decades of Medicare coverage of ESRD, the Government has made substantial changes to the design of the program with the goal of supporting the health of beneficiaries while aligning the financial incentives of health care providers.

49. On one hand, the ESRD program seeks to promote efficient health care delivery by allowing providers to profit from their own efficiencies and lower costs. It does this by bundling many dialysis-related services and products into a single, prospective composite payment rate ("PPS"). Providers are paid this fixed rate per treatment regardless of their individual cost, so they can profit if the reimbursement exceeds those costs and will incur losses if their costs are greater than the reimbursement.

50. On the other hand, the ESRD program seeks to ensure that providers are not sacrificing quality to increase profits under the PPS. In furtherance of this goal, the Government has established the Quality Incentive Program, through which it evaluates ESRD providers annually on a series of quality metrics, publishes those metrics, and will reduce Medicare reimbursements by up to 2% for providers that fail to meet applicable baseline standards.

51. The PPS composite rate covers a wide range of comprehensive ESRD treatments including the cost of dialysis machines, the dialysis treatment itself, and certain other procedures and drugs related to the administration of dialysis to a patient. Specifically, the PPS composite rate covers the dialysis access monitoring function, which is the responsibility of the dialysis treatment provider.

52. In addition, Medicare will cover limited other treatments that allow dialysis to function effectively, such as certain procedures determined by a physician to be necessary for a patient's dialysis, where those treatments are separately billed and justified.

53. In no event will Medicare reimburse ESRD providers for the costs of any treatments that are not reasonable and necessary to the beneficiary.

C. Medicaid, TRICARE, And The VA Program

54. Medicaid is a joint federal-state program that provides health care benefits for the poor and disabled. Medicaid is funded by both federal and state dollars. The federal portion of each state's Medicaid payment, known as the Federal Medical Assistance Percentage ("FMAP") is based on the state's per capita income compared to the national average. *See* 42 U.S.C. § 1396d(b). The FMAP currently ranges from approximately 50% to 71% depending on the state.

55. Depending on the specific rules in place in a given state, Medicaid may cover patient copays and deductibles for individuals with Medicare coverage of ESRD. For instance, Medicare coverage for individuals with ESRD typically begins at least three months after the initiation of dialysis treatment, and Medicaid will cover eligible individuals during that initial three month period. Medicaid programs also provide ESRD coverage for the first 90 days of a patient's treatment, which is not covered by Medicare.

56. Like Medicare, Medicaid will not pay for treatments that are not medically necessary or appropriate. *See e.g.*, 18 N.Y.C.R.R. § 500.1(b); N.J.A.C. 10:49-5.1(a)(1).

57. Fresenius Medical Care has estimated that Medicare and Medicaid are the primary payers for 76% of their patients in North America.

58. TRICARE is a government-funded health care program for active and retired members of the American uniformed services and their families. TRICARE covers dialysis and ESRD-related services for its members. For members who are primarily covered by Medicare, TRICARE will pay the Medicare deductible and patient cost share. *See* 10 U.S.C. §§ 1071-1110.

59. TRICARE uses standards applicable to Medicare for the scope of its coverage and will not reimburse for medically unnecessary procedures. *See* 10 U.S.C. § 1079(j)(2); 32 C.F.R. § 199.4(a)(1)(i).

60. The VA Program is a government-funded health care program for veterans and provides coverage for dialysis and related services. Fresenius Medical Care acknowledges in its public filings that it receives reimbursements from the VA Program. *See* FMC 2013 20-F, at 44.

61. References in this Complaint to the "Government" include the federal health care programs – Medicare, Medicaid, TRICARE, and the VA Program – and the Medicaid programs of the Plaintiff States.

D. Specific Rules for Medicare Coverage of Vascular Access Procedures for ESRD Patients

62. The Medicare Claims Processing Manual, which contains the guidelines for Medicare reimbursement of vascular access procedures, directs that monitoring vascular access is the ongoing responsibility of the dialysis treatment provider and that payment for such monitoring is included within the composite (bundled) rate Medicare pays the provider for treating the ESRD patient:

> For dialysis to take place there must be a means of access so that the exchange of waste products may occur. As part of the dialysis treatment, ESRD facilities are responsible for monitoring access, and when occlusions occur, either declot the access or refer the patient for appropriate treatment. Procedures associated with monitoring access involve taking venous pressure, aspirating thrombus, observing elevated recirculation time, reduced urea reduction ratios, or collapsed shunt, etc. All such procedures are covered under the composite rate.

Medicare Claims Processing Manual ("Claims Manual"), Chapter 8, § 180.

63. Monitoring of venous pressure allows the treating medical staff to confirm that a patient's blood flow is at a sufficient level to permit effective dialysis. Pressure that is too high is an indication that dialysis may be impaired.

64. A thrombus is a blood clot, and when identified may be removed from a patient's blood vessels by "aspiration," which involves the insertion of a tube (catheter) into the affected blood vessel and removal of the clot through suction.

65. Recirculation is a condition in which not all of the blood that is directed into a patient's body from the dialysis machine flows in the direction intended. When blood "recirculates" in the wrong direction it indicates that the patient's vascular system is not permitting the full functioning of dialysis.

66. Urea reduction ratios measure the extent to which dialysis is successful in removing toxins (urea) from the patient's blood. Lower measures of urea reduction are an indication that dialysis is not functioning properly.

67. A shunt is a connection between an artery and vein that bypasses the system of capillaries. A hemodialysis fistula is a type of shunt that directly connects an artery and vein. If a patient's shunt or fistula collapses it may be unable to support sufficient blood flow for dialysis.

68. Under Medicare, "vascular studies [which would include a fistulagram] are not covered as a separately billable service if used to monitor a patient's vascular access site." Claims Manual Ch. 8, § 180. "Routine monitoring … is included under the ESRD PPS." Medicare Benefit Policy Manual ("Benefit Manual"), Ch. 11, § 40.H.

69. Medicare provides examples of conditions detected in the course of vascular access monitoring that support a finding of "medical necessity" for vascular studies such as fistulagrams:

- Elevated dynamic venous pressure >200mg HG when measured during dialysis with the blood pump set on a 200cc/min.,
- Access recirculation of 12 percent or greater,
- An otherwise unexplained urea reduction ratio <60 percent, and
- An access with a palpable "water hammer" pulse on examination (which implies venous outflow obstruction).

Benefit Manual, Ch. 11, § 40.H.

70. National Government Services, Inc. ("NGS"), the regional Medicare administrator for New York and a number of other states has issued Medicare reimbursement guidance in the form of a Local Coverage Determination ("LCD") with regard to dialysis access maintenance. It provides that fistulagrams and angioplasties are medically necessary if and when they are "intended to restore and /or maintain functional patency of the access." Thus, clinical findings must indicate that the functionality of the fistula has been impaired:

> When diagnostic non-invasive vascular studies are performed to evaluate an AV access [fistula] on a routine basis in the absence of signs and symptoms the services are considered monitoring and are not separately covered by Medicare.
>
> In the absence of clinical findings suggesting the need to re-establish appropriate flow in a dialysis fistula, it is seldom reasonable and necessary to perform diagnostic angiography [fistulagrams] … as part of the decision to treat (*i.e.*, CPT codes 75710, 75820, 93990).
>
> *****
>
> Claims will not be paid if documentation in the medical record (e.g., procedure report) does not verify that the services described by the submitted CPT codes were provided and/or were not medically necessary.
>
> Medicare does not pay for services that are screening in nature or that are not providing clinically relevant information.

Local Coverage Determination (LCD) for Dialysis Access Maintenance (L30737), effective 6/1/2010 through 12/29/2012 (emphasis added); *see also* Local Coverage Article, Dialysis Access Maintenance – Medical Policy Article (A52839), effective from 10/1/2015 to present; Local Coverage Article (A51630), effective 3/1/2012 through 9/30/2015 (same).

71. Under the heading "Utilization Guidelines," this LCD explains: "Services performed with excessive frequency will be denied as not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and reasons for additional services are not justified by documentation." *See also* Local Coverage Article (A52839).

72. This guidance is consistent with NGS's requirements with regard to non-invasive vascular studies:

> Non-invasive vascular studies are considered medically necessary if the ordering physician has reasonable expectation that their outcomes will potentially impact the clinical management of the patient. Services are deemed medically necessary when the following conditions are met:
>
> - Significant signs/symptoms of arterial or venous disease are present;
> - The information is necessary for appropriate medical and/or surgical management; and/or
> - The test is not redundant of other diagnostic procedures that must be performed.
>
> In general, non-invasive studies of the arterial system are utilized when invasive correction is contemplated. It is the responsibility of the physician/provider to ensure the medical necessity of procedures and documentation of such in the medical record.

Local Coverage Determination (LCD) for Non-Invasive Vascular Studies (L27355), effective 11/15/2008, revised 1/1/2012 (emphasis added), superseded on 10/1/2015 by L33627 (same).

73. This LCD also provides unambiguous direction that a physician referral must be documented for each procedure: "A referral must be on record for each non-invasive study performed. A referral for one type of study does not qualify as a referral for all tests." (Emphasis added.)

VI. MONITORING VASCULAR ACCESS, DIAGNOSTIC TESTING FOR DETERMINING THE CAUSE OF A VASCULAR DYSFUNCTION, AND PROCEDURES FOR CORRECTING A VASCULAR DYSFUNCTION

A. Standard Monitoring Of Vascular Access By A Patient's Dialysis Center, And Referrals For Vascular Access Procedures

74. Most individuals with ESRD require dialysis, where medical procedures and devices are used to replicate the blood cleaning functions that would be performed by healthy kidneys. This often requires a patient to undergo dialysis treatments three times a week for an indefinite period of time.

75. Most patients receive their dialysis treatment at outpatient dialysis centers. Each treatment can last three to five hours, and includes the dialysis itself as well as a series of standard monitoring tests to confirm that the dialysis is working effectively. The patient will typically be seen by a nurse, under the supervision of a nephrologist.

76. To gain access to a patient's vascular system to perform dialysis, there must be a point of entry to connect the dialysis machines to the patient with a sufficient blood flow rate. A common solution is to surgically create a "fistula" – an artificial connection of a major vein and artery that is close enough to the skin's surface to permit access for dialysis.

77. When a patient undergoes dialysis treatment, the medical staff is responsible for performing a series of standard monitoring, surveillance, and if medically indicated, diagnostic procedures to determine whether the dialysis is functioning effectively or whether the patient has a condition that is impairing its proper functioning. This standard protocol includes:

(a) Monitoring: At least monthly, medical staff should perform physical evaluations of the patient to detect dysfunction of the fistula or other vascular access site.

(b) Surveillance: Evaluations of intra-access blood flow, static vascular dialysis pressure, recirculation, and other measures that suggest dialysis dysfunction.

(c) Diagnosis: Specialized testing that is prompted by an abnormality or medical indication undertaken to diagnose the cause of a vascular access dysfunction.

See Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines for Vascular Access ("KDOQI Guidelines"), Guideline 4.

78. When the results of monitoring tests show problems at the point where the dialysis machine connects to a patient's vascular system (the vascular access site) that are preventing dialysis from effectively cleaning a patient's blood, the treating physician may refer that patient to a vascular access center to diagnose the cause and, if appropriate, perform a procedure to enable dialysis to function properly.

79. It is the nationwide network of vascular access centers owned and operated by Fresenius that is perpetrating the fraud described in this Complaint by performing unnecessary procedures purportedly to restore vascular access in dialysis patients but in reality to steal funds from the Government.

80. The procedure that Fresenius vascular access centers use to identify blockages in blood flow is called a fistulagram or an angiogram. The procedure that Fresenius vascular access centers use to address purported blockages in blood flow is an angioplasty.

81. A fistulagram is a type of angiogram in which an X-ray of an artery or vein at the fistula is performed by penetrating a patient's skin and blood vessels, inserting small tubes (catheters) into the blood vessels, injecting contrast dye through the catheters, and taking X-rays of the dyed blood vessels.

82. Fresenius also performs angiograms on peripheral arteries and veins (those in patients' arms or legs).

83. In connection with performing fistulagrams and angioplasties, Fresenius also inserts stents into patients' vasculature.

84. Patients receiving a fistulagram or angiogram may be given pain medication or a sedative and may be restricted from driving for a period of time.

85. For patients that have a stenosis (narrowing) that is "hemodynamically significant" (generally, a reduction in blood flow through the fistula that is below the dialysis machine's requirement for adequate treatment) in their fistula or surrounding blood vessels, an angioplasty may be a proper procedure to expand the narrowed vessel so that sufficient blood flow for dialysis can be restored.

86. An angioplasty involves the penetration of a patient's skin to insert a tube (catheter) with a small balloon at one end into a blood vessel. The catheter will be guided through the patient's blood vessel until it reaches an area of narrowing, at which point the balloon will be inflated to widen the vessel.

87. Procedures such as fistulagrams, angiograms, and angioplasties can present significant risks to the patient. They can cause infection, allergic reaction, rupture of blood vessels, and/or internal or external bleeding.

88. In addition, exposure to the iodine-containing dye used in radiological procedures may have an adverse impact on residual kidney function. Residual kidney function "is one of the most important predictors of a patient's survival." KDOQI Clinical Practice Guidelines for Hemodialysis Adequacy, Guideline 6. Accordingly, it is recommended that this contrast dye be avoided as a means of preserving residual kidney function. *Id*. Clinical Practice Recommendation 6.

B. Diagnostic Fistulagrams, As Well As Angiograms, Can Only Be Reasonable And Necessary When Monitoring Modalities Indicate That A Patient's Dialysis Treatment Is Impaired

89. The National Kidney Foundation publishes the National Kidney Disease Outcomes Quality Initiative ("KDOQI") to provide evidence-based clinical practice guidelines for the treatment of patients with ESRD. The KDOQI is generally accepted as the leading source for kidney disease treatment professional guidelines, and is cited on Fresenius's website.

90. With regard to diagnostic procedures, the KDOQI states, "One should not respond to a single isolated abnormal value. With all techniques, prospective trend analysis of the test parameter has greater power to detect dysfunction than isolated values alone." KDOQI Guideline 4.4.1.

91. In addition, medical staff are to refer a patient for vascular access imaging when there are "persistent abnormalities" in the monitoring or surveillance parameters. KDOQI Guideline 4.4.2.

92. Specifically with regard to intervention on a fistula, the KDOQI directs that intervention should be performed for those stenosis (narrowing of blood vessels) that are "hemodynamically significant." KDOQI Guideline 5.2.2.

93. In the case of fistulas it may be "difficult to describe reliably the percentage of narrowing" in a blood vessel, so the KDOQI directs that the parameters for determining whether a stenosis is "hemodynamically significant" for a fistula include both a narrowing greater than 50% and other supportive clinical symptoms, abnormal physical findings, and flow measurements. *See* KDOQI Guideline 5.3, and related commentary.

94. The KDOQI Working Group makes this point clear: "Stenotic lesions should not be repaired merely because they are present." KDOQI 2006 Updates Clinical Practice Guidelines and Recommendations ("KDOQI Updates"), at 294.

95. Angioplasties should only be used to address stenoses that impair dialysis function and interventionalists performing the procedures should conduct before-and-after clinical tests to demonstrate that the angioplasty actually improved dialysis function: "If such correction [of stenosis] is performed, then intraprocedural studies of [vascular pressure and blood flow] before and after [angioplasty] should be conducted to show a functional improvement with a 'successful' [angioplasty]." KDOQI Updates, at 294.

96. The Centers for Medicare and Medicaid Services have implemented a Quality Incentive Program designed to encourage high quality and cost-effective healthcare services for ESRD patients. As part of this effort, CMS has identified as a measure of adequate dialysis that patients have a clinical measure ("Kt/V") equal to or greater than 1.2. *See* 78 Fed. Reg. 72191 (Dec. 2, 2013).

97. Fresenius has acknowledged the importance of the Kt/V metric by using it as a reference point to demonstrate the quality of dialysis administered at its own dialysis centers. *See* Fresenius Medical Care North America 2014 Annual Medical Quality Report at p. 18 (describing CMS clinical measure and noting that 94.5% of its own dialysis patients maintained Kt/V rates equal to or greater than 1.2 in 2013).

98. Distinguishing conditions that functionally impair dialysis from commonly-occurring findings that are simply abnormal anatomically but do not impair a patient's ability to receive dialysis is a critical aspect of assessing fistula function. If a provider cannot determine whether a patient's condition actually impairs dialysis, then that provider cannot properly ascertain whether a given procedure is reasonable or necessary, and therefore cannot demonstrate that such procedure is covered by Medicare.

99. ESRD patients often have narrowings (stenoses) of their veins and arteries that do not limit the provision of effective dialysis. Further, it is commonly believed that angioplasty of these asymptomatic narrowings actually is counterproductive since the procedure injures the walls of the vein or artery and leads to scarring and subsequent worsening of the stenosis. Procedures to detect and remove these non-material narrowings subject patients to unnecessary health risks such as infection, allergic reaction, and internal bleeding. Patients also risk the loss of residual renal function caused by the contrast dye used in such procedures.

100. An analogy can be made to routine wear on the tires of a car. Almost every car on the road has some level of wear on its tires, although most are still perfectly able to function safely. In determining whether to have a set of tires replaced, the proper test is not whether there is any wear on them (there always will be), but whether the car can be safely driven. Similarly here, the proper test is not whether some narrowing of a blood vessel is observed, but whether dialysis can be effectively performed on that patient.

101. Accordingly, the KDOQI directs providers who visually observe signs of stenosis to look to other clinical measures to determine whether (even if a narrowing is present) there is any corroborating evidence to indicate that dialysis is impaired. *See* KDOQI Guideline 5.3.

VII. THE CALIFORNIA INSURANCE FRAUDS PREVENTION ACT

102. In 1993, the California Legislature enacted the Insurance Frauds Prevention Act ("IFPA") to combat insurance fraud. In the preamble to the IFPA, the Legislature declared and found that "the business of insurance involves many transactions that have the potential for abuse and illegal activities. There are numerous law enforcement agencies on the state and local levels charged with the responsibility for investigating and prosecuting fraudulent activity. This chapter is intended to permit the full utilization of the expertise of the commissioner and the department

so that they may more effectively investigate and discover insurance frauds, halt fraudulent activities, and assist and receive assistance from federal, state, local, and administrative law enforcement agencies in the prosecution of persons who are parties in insurance frauds." Cal Ins. Code § 1871.7, subd. (a).

103. With regard to healthcare fraud in particular, the Legislature found and declared: "Health insurance fraud is a particular problem for health insurance policyholders. Although there are no precise figures, it is believed that fraudulent activities account for billions of dollars annually in added health care costs nationally. Health care fraud causes losses in premium dollars and increase health care costs unnecessarily." Cal Ins. Code § 1871(h).

104. To combat this fraud, in pertinent part, the IFPA prohibits various forms of insurance fraud and additionally imposes civil liability for violations of California Penal Code section 549, 550, and 551. Cal. Ins. Code § 1871.7(a)-(b).

105. Among the conduct for which the IFPA imposes liability is the violation of California Penal Code § 550. Defendants have violated numerous provisions of these statutes by themselves or by aiding, abetting, soliciting, or conspiring with others to:

(a) Knowingly present or cause to be presented false or fraudulent claims for the payment of a loss or injury under a contract of insurance (Cal. Penal Code § 550(a)(1));

(b) Knowingly prepare, make, and/or subscribe any writing, with the intent to present or use it, and/or to allow it to be presented, in support of any false or fraudulent claims (Cal. Penal Code § 550(a)(5)); and

(c) Knowingly make, and/or cause to be made false and/or fraudulent claims for payment of a health care benefit (Cal. Penal Code § 550(a)(6)).

106. In addition, Defendants did or knowingly assisted or conspired with others to:

(a) Present or cause to be presented written or oral statements as part of, or in support of, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false and/or misleading information concerning any material facts (Cal. Penal Code § 550(b)(1));

(b) Prepare and/or make written and/or oral statements intended to be presented to any insurer or any insurance claimant in connection with, and/or in support of claims and/or payments and/or other benefits pursuant to an insurance policy, knowing that the statements contained false and/or misleading information concerning material facts (Cal. Penal Code § 550(b)(2)); and

(c) Conceal or knowingly fail to disclose the occurrence of an event that affects any person's initial and/or continued right and/or entitlement to any insurance benefit and/or payment, and/or the amount of any benefit and/or payment to which the person is entitled (Cal. Penal Code § 550(b)(3)).

VIII. FACTUAL ALLEGATIONS

A. Fresenius Faces A Challenging Economic Environment And Pressure From The Market To Increase Revenue And Profits

107. During the time period of Defendants' fraudulent scheme, the global economic environment for health care providers has undergone substantial changes and put pressure on top Fresenius executives to increase the company's revenue and profits.

108. Approximately 76% of Defendant's North America patient base is covered by the Government through Medicare and Medicaid, so the dollar volume of Government reimbursement plays a critical role in Defendants' overall financial condition. FMC 2013 Form 20-F, at 7.

109. In Fresenius's 2013 Annual Report, its CEO stated that the U.S. was "such a crucial market" and that declining reimbursement rates for dialysis treatments "hit us hard, and will significantly impact our earnings growth again at least in 2014." FMC 2013 Annual Report, at 14.

110. Fresenius's 2013 Annual Report further explained, "The sustained debate on reimbursement cuts for dialysis treatment in our most important market, the U.S., and elsewhere had an adverse effect on our share price performance and led to pronounced share price fluctuations." FMC 2013 Annual Report, at 28.

111. In February 2014, Fresenius announced that it projects calendar year 2014 profit to fall for the second straight year. This news caused Fresenius's stock price to immediately fall nearly 6%. Declining revenue was attributed in part to decreased health care spending by the U.S. government.

112. The challenging economic and market environment for Fresenius appears likely to continue. Fresenius's CEO stated that "although the [U.S. Medicare] reimbursement rate will be at a similar level in 2014 and 2015 compared with 2013, it will no longer cover the increase in treatment costs caused by inflation." FMC 2013 Annual Report, at 15.

113. One of Fresenius's strategies to survive this challenging environment is to focus on generating revenue from its vascular access segment. When asked for specific ideas to guide the company forward, Fresenius's CEO reassured its shareholders that the company has "started a network of dialysis-related services such as vascular access … which we plan to expand in the future." FMC 2013 Annual Report, at 16.

114. Fresenius has combined its non-dialysis services, including Fresenius Vascular Care and other intervention clinics, into a new division it calls "Care Coordination." As

explained in its 2015 Annual Report: "Care Coordination enables us to expand and increase the growth of our business beyond dialysis …. With our activities in the Care Coordination division and our experience in dialysis, we can help to shape the evolution of the health care system and use this as a basis for additional growth." FMC 2015 Annual Report at 35.

115. Fresenius's acquisition and integration of American Access Care in 2011 and additional vascular access centers such as National Cardiovascular Partners in 2014, has spurred the rapid revenue growth of Fresenius's "Care Coordination" business. Care Coordination was by far Fresenius's fastest-growing segment in 2015 with revenues of over $1.8 billion, an 81% increase over 2014. *Id*. at 72.

116. Fresenius has budgeted an additional investment volume of up to $3 billion to grow its Care Coordination division from its current 11% of total company revenue to 18% by 2020. *Id*. at 41.

117. However, revenue from vascular access centers is dependent on a constant stream of physician referrals. As Fresenius has warned its shareholders:

> The decision to purchase or prescribe our dialysis products and other services or competing dialysis products and other services will be made in some instances by medical directors and other referring physicians at our dialysis clinics and by the managing medical personnel and referring physicians at other dialysis clinics, subject to applicable regulatory requirements. A decline in physician recommendations or recommendations from other sources for purchases of our products or ancillary services would reduce our dialysis product and other services revenue, and would materially adversely affect our business, financial condition and results of operations.

Fresenius Medical Care AG & Co. KGaA 2015 Form 20-F at 12.

B. The Defendants' Fraudulent Scheme To Self-Refer Patients For Unnecessary Procedures And Falsify Records To Obtain Payment For Non-Covered Treatment

118. Defendants own and operate a number of health care facilities that, among other things, perform vascular access procedures such as fistulagrams (x-rays of fistula), angiograms (x-rays of blood vessels), and angioplasties (widening of blood vessels by inserting and inflating a small balloon). When properly administered, these procedures can improve the efficacy of dialysis treatments.

119. Patients on dialysis are constantly monitored by medical staff to ensure that their dialysis is functioning effectively. These routine tests include the monitoring of blood flow, blood vessel pressure, waste removal measures, and other metrics.

120. Indeed, most of these tests can only be performed while dialysis is underway. These monitoring activities provide the treating medical staff with the highest quality indications of whether there are any obstructions in a patient's vascular system that rise to the level of impeding dialysis treatment.

121. Specifically, routine surveillance of access flow and venous pressures during dialysis are the preferred methods for evaluating the performance of dialysis and the detection of stenosis. *See* KDOQI Guideline 4.2.

122. Furthermore, the usefulness of other procedures to determine the presence of stenosis <u>without</u> reference to these measurements has not been demonstrated:

> [T]he value of routine use of any technique for detecting anatomic stenosis alone – without concomitant measurement of access flow, venous pressure, recirculation, or other physiological parameters – has not been established.

KDOQI Updates, at 294.

123. When medical staff determines that a patient's vascular access is compromised to the point of interfering with dialysis, it may refer that patient to one of Defendants' clinics for a

one-time procedure to identify the source of the obstruction and restore sufficient vascular access.

124. According to the standards of practice in the professional community, vascular access facilities like Defendants' should perform procedures to address the condition for which patients were referred to them and communicate the results of those procedures to the patient's treating physicians who will modify the patient's course of treatment accordingly.

125. Instead, Defendants have taken a different course, designed to profit at the expense of taxpayer funds and the health risks of their patients.

126. Once Defendants perform the referred procedure, as a matter of practice they typically schedule a "follow-up" visit directly with the patient without consulting the patient's treating medical team, and in reckless disregard of the medical needs of the patient. The patient's discharge instructions not only include the date of the next appointment, but direct the patient not to eat or drink for 8 hours immediately prior to the appointment.

127. Not only did these follow up visits – which almost always entailed a fistulagram plus an angioplasty – routinely take place without any referral from the treating physician, Defendants never even asked the dialysis center for the patient's recent dialysis records prior to performing fistulagrams and angioplasties to determine if they revealed clinical indications of impaired functionality of the fistula. Thus Defendants chose to perform the fistulagram and angioplasty without the benefit of knowing this highly relevant, indeed critical, patient information. On information and belief, on occasion non-physician personnel from Defendants' access centers have called non-physician personnel at patients' dialysis centers to request a last-minute referral, claiming that the patient (who in fact had a scheduled appointment with Defendants for months) had suddenly arrived at Defendants' access center with symptoms of

fistula impairment. Defendants no doubt deliberately chose to blind themselves to critical patient information because they recognized full well that since the dialysis center had not seen fit to refer the patient to the vascular access center, the patient's dialysis records would reveal that the patient's fistula was functioning properly and that neither a fistulagram nor an angioplasty was reasonable or medically necessary.

128. In connection with the unnecessary fistulagrams and angioplasties that Defendants perform on a periodic basis, Defendants also insert stents into patients' vasculature. These stents are often inserted with no medical justification and are therefore not "reasonable and necessary" and reimbursable by Medicare and Medicaid. Furthermore, the excessive insertion of stents subjects patients to increased risk of infection and other side effects.

129. Defendants' self-referral scheme was alluded to in or around the Spring of 2011, several months before Fresenius purchased American Access Care in October 2011. At that time, Dr. Gregg Miller, the Chief Medical Officer of AAC, approached Dr. John Pepe in an unsuccessful attempt to purchase his dialysis practice.

130. In the course of their discussions, Miller told Dr. Pepe that if a dialysis center was owned by American Access Care (or its new parent, Fresenius) the company could self-refer patients from its dialysis center to its vascular access clinics. Implicit in this statement was an acknowledgement that a patient's treating physician must refer that patient to a vascular access center for each procedure.

131. Gregg Miller was immediately installed in a leadership position as Chief Medical Officer at FVC after its October 2011 acquisition of AAC. He has risen even higher in the organizational ranks since then. Moreover, he has repeatedly made public presentations to physicians on behalf of Fresenius endorsing the use of surveillance fistulagrams. Defendant

Miller laid out Fresenius' philosophy on surveillance fistulagrams and preventative angioplasties at the February 2013 Annual Meeting of the American Society of Diagnostic and Interventional Nephrology (ASDIN) in Washington D.C.. During a "Point/Counterpoint" session, Miller made a presentation regarding why patients should return for scheduled follow-up elective fistulagrams after access intervention. Among other representations, Miller falsely claimed to the audience that Medicare does not reimburse the dialysis center for monitoring the fistula. In truth, of course, payment for monitoring is included within the composite reimbursement rate.

132. In a powerpoint used for his presentation called "Is There Value to an Elective Fistulagram After Previous AV Access Intervention," Dr. Miller acknowledges that "stenotic lesions should not be repaired merely because they are present," and that "Medicare does not reimburse for vascular access surveillance," but notwithstanding these concessions, he proceeds to set forth Fresenius's justification for elective "Follow-up Fistulagrams."

133. Dr. Miller states that "Follow-up fistulagrams" should be performed at periodic intervals that are "ideally … just before" clinical measures of dialysis function decline. Tellingly, the presentation then states that "it is impossible to predict when the aforementioned conditions will result in inefficient [dialysis] treatments." However, "Follow-up fistulagrams" that are done admittedly before any clinical indication of their necessity are surveillance procedures that are not reimbursable. Indeed, this is why Medicare requires a referral from the treating physician to substantiate the fact that in the course of performing the monitoring function, signs and symptoms of impaired dialysis function were observed.

134. Defendants had to entice patients, who were already undergoing dialysis treatment three times a week, to show up for repeat procedures and on repeated occasions did so by providing free transportation, oftentimes in a limousine, and free meals upon arrival.

135. The Health and Human Services Office of the Inspector General ("OIG") has issued Advisory Opinions regarding when the provision of free transportation to patients violates federal law, including the Anti-Kickback Statute. The OIG has concluded that free limousine services are an example of potentially abusive arrangements that lead to "inappropriate steering of patients, overutilization, and the provision of medically unnecessary services." OIG Advisory Opinion No. 09-01 (Mar. 6, 2009).

136. Specifically, the OIG stated that "[l]uxury or specialized transportation, such as limousines, airline tickets, or ambulance transports, raise greater concerns because such transports are more valuable to the recipient and therefore more likely to be an improper inducement." OIG Advisory Opinion No. 09-01.

137. The free limousine service provided by Defendants' facilities in Staten Island was precisely the type of "abusive arrangement" that was used to induce patients to "self-refer," or to voluntarily appear for unnecessary procedures.

138. Both of Defendants' facilities in Staten Island discussed above are located on or near main roads, with accessible public transportation (bus and train) nearby.

139. In addition, the market value of a round-trip limousine ride was likely in excess of $100 per trip – far above the $10 per item and $50 per year "nominal value" limits set by OIG. *See* 65 Fed. Reg. 24400, 24411 (April 26, 2000).

140. New York State's Anti-Kickback Statute, 18 N.Y.C.R.R. § 515.2(b), similarly prohibits kickbacks relating to the provision of medical care covered by Medicaid.

141. Defendants would also call patients at home to urge them to return, and went so far as to tell patients that their dialysis treatment would not be successful if they did not return for repeat procedures.

142. When the daughter of one of Dr. Pepe's patients questioned Fresenius interventionalist, Dr. William Rodino, as to why her father was being subjected to so many repeat procedures, Rodino effectively admitted he was performing "surveillance angiograms." Dr. Rodino told her that even when dialysis center monitoring indicates normal dialysis function, it may "miss something" that Fresenius will "find" with a fistulagram.

143. Additionally, many of the patients that Defendants lured or pressured into repeat medical procedures had a primary language other than English. On information and belief, Defendants did not provide language access services to these patients to ensure they could communicate effectively with Defendants' staff, as required by federal law.

144. This type of persuasion on a vulnerable population would have been unnecessary if Defendants' appointments and procedures were needed, since the patients' treating doctors and nurses – who administer dialysis to them every other day – would have identified any problems with dialysis and referred them for any outside treatment that was necessary.

145. This is in direct violation of Medicare reimbursement laws and professional standards, as well as Fresenius's own Code of Business Conduct, which states that "Patient care should be guided by the intended outcome of the patient's treatment plan in accordance with established clinical standards and protocols." Fresenius Medical Care North America Code of Business Conduct ("Code of Conduct").[1]

146. These "follow-up" procedures were entirely self-referred and the patient records created by Defendants were falsified to either provide no reason at all for the follow-up, or to

[1] The Code of Conduct can be found on Fresenius Medical Care North America's website at http://www.fmcna.com/fmcna/compliance/compliance.html (last visited May 28, 2014).

provide an insufficient reason, such as to monitor for vague, future problems. However, Medicare does not cover fistulagrams that are performed only for monitoring purposes.

147. Patient records were also falsified to indicate that future visits were referred by the treating physician who made the initial referral, rather than by Defendants themselves.

148. Defendants' own Code of Conduct, however, directs that "Clinical care must be based on patient medical needs and physician orders." (Emphasis added.)

149. Defendants induced patients to return for numerous additional visits and procedures with free food and limousine transportation, knowing that many of their patients were disadvantaged minorities, elderly, and low-income individuals.

150. Again, this violated Defendants' own Code of Conduct: "[G]ifts or other benefits may not be used to improperly influence a patient's choice of Fresenius as his or her dialysis provider." Furthermore, the Code of Conduct acknowledges that "[f]ederal law prohibits making payments or offering other benefits to patients for the purpose of influencing their choice of a particular provider," which includes "[r]outine reimbursement of transportation costs."

151. When patients arrived at their non-referred follow-up appointments, the "examination" was a mere pretext designed to allow Defendant to invent a justification for performing an expensive procedure. At these visits, the Defendant would routinely observe some purported "pulsing" or "thrill" (vibratory sensation) on visual exam of the patient and would immediately perform an unnecessary procedure without conferring with her treating physician or even referencing clinical data from recent dialysis sessions.

152. In many instances, the clinical data that was observed and recorded by a patient's treating medical staff during dialysis would have disclosed that recent (meaning within the last several days) monitoring of the patient's vascular access had detected no impairment of the

dialysis function. This information that Defendants chose not to access or listen to was critical to a proper determination of whether a fistulagram or angioplasty was warranted in a given case.

153. Defendant's website contains a video entitled "The 1-Minute Fistula Examination."[2] This video illustrates the limited physical examination on which Defendants rely to justify hundreds or thousands of unnecessary procedures each year. Disregarding the substantial, documented clinical data that is generated from patients' ongoing dialysis, Defendants perform a physical exam that lasts literally a few seconds and on that basis alone initiate repetitive and unnecessary procedures to inflate their revenue and defraud the Government.

154. This practice violates federal law, professional standards of practice, and Defendants' own Code of Conduct, which directs that "[a]ll billings for healthcare items and services must be truthful and accurate, and should conform to applicable legal and contractual requirements …. Appropriate records must be available to document that all services meet these standards, including proper documentation of medical necessity."

155. Not satisfied to use each patient to generate only one or two visits of fraudulent billing, Defendants in some cases would self-refer patients as many as ten times over two years for unnecessary procedures.

156. Defendants would even self-refer and perform unnecessary angiograms and angioplasties unrelated to dialysis fistulas on Dr. Pepe's patients, especially those with diabetes or peripheral artery disease. This increased the number of procedures for which they fraudulently billed Medicare and Medicaid.

[2] http://freseniusvascularcare.com/1-minute-fistula-examination.php (last visited May 28, 2014).

157. Touchstone Health, a Medicare Advantage insurer, recently denied a request by Defendants for a "routine follow up in addition to a number of potential interventions for the fistula" on one of Dr. Pepe's dialysis patients who was being treated at the FVC facility operating as Verrazano Vascular Associates. The Notice of Denial of Medical Coverage stated that "there are no reports that you are currently having inadequate or problematic dialysis" from the dialysis center as would justify further vascular intervention, and therefore denied coverage due to lack of medical necessity.

158. Touchstone Health's Notice of Denial of Medical Coverage acknowledged that vascular intervention on a patient's fistula is medically necessary only when it results in impairment to dialysis and is specifically referred by an ESRD patient's treating physician: "The request may be reconsidered if your dialysis center refers you to the vascular surgeon because you are having current problems with your dialysis."

159. This fraudulent scheme has been in operation since at least October 2011 and continues to the present day, resulting in losses estimated by the professional expertise of Relators to be in the hundreds of millions of dollars.

C. Specific Examples Of Fraudulent Claims

160. Paragraphs 163 through 243 contain specific factual allegations of individual Medicare patients who were subjected to Defendants' fraudulent scheme of unnecessary procedures. The examples necessarily have minor differences from each other, but taken together clearly demonstrate that Defendants are operating from a generic playbook that involves a combination of the following aspects regardless of the individual medical needs of each patient:

(a) After performing the procedure that was initially referred to them from a patient's treating physician, Defendants will invent a pretext to self-refer a follow-up "exam" while not conferring with the treating physician that Defendants directed the patient to return for this follow-up appointment.

(b) To hide their blatant self-referral and in an attempt to demonstrate the (non-existent) medical necessity of subsequent procedures, Defendants will falsely indicate on patient records that the subsequent visits were referred by the patient's treating physician.

(c) At the subsequent "follow-up", Defendants will manufacture a vague, subjective visual observation such as a "pulsatile" blood vessel.

(d) Defendants will either not request or ignore documentation from the patient's recent dialysis treatments – which often occurred the day before – that demonstrates with quantifiable clinical tests that there is no impairment of the dialysis process.

(e) Defendants will make no attempt to corroborate their unsubstantiated visual observation with the types of clinical tests that professional standards require before initiating a time-consuming and potentially harmful procedure.

(f) Defendants will perform one or more unnecessary fistulagrams, angiograms, and/or angioplasties on a patient to inflate their Medicare revenues in reckless disregard of the medical needs of the patient.

(g) Defendants will repeat this pattern multiple times to fraudulently generate as much revenue from each patient as possible without arousing suspicion.

(h) Additionally, according to several patients of Dr. Pepe, Defendants threatened patients that if they did not undergo repeated "exams" at Defendants' facilities, their fistula may narrow to the point where dialysis would be impossible.

161. The vast majority of Relator's ESRD patients are Medicare beneficiaries. Additionally, a substantial portion of his patients are eligible for both Medicare and Medicaid due to the fact that many are of very limited financial means.

162. On information and belief, Defendants utilize uniform operational and billing procedures across their nationwide network of vascular access centers. The practices set forth by the following examples and described throughout this Complaint are therefore illustrative of the practices followed across Defendants' corporate structure and chain of vascular access centers.

Patient 1 (A.G.)

163. Patient AG is a 72 year-old female who began kidney dialysis in December 2011. AG was initially referred to Defendants in 2012 by her treating physician at the Staten Island Artificial Kidney Center, Dr. Matthew Palombini, for procedures relating to the removal and replacement of her catheter with a fistula.

164. Once her fistula was created and had matured by July 2012, the procedures for which she was referred to Defendants were complete and there was no medical need for Defendants to perform additional procedures.

165. However, after her initial (properly referred) visits and procedures, which concluded on July 23, 2012, Defendants continuously and repeatedly scheduled AG to return to their facility for "follow-up" appointments that always generated new procedures, and falsely indicated that these procedures were referred by her treating physician, Matthew Palombini.

166. Specifically, these follow-up appointments and procedures were scheduled and performed by Dr. William Rodino and Dr. Frank Tarantini, both of Verrazano Vascular Associates. Verrazano Vascular Associates is part of the Fresenius Vascular Care network, and is alternatively referred to in its own documents as "Access Care Physicians of New York,"

"American Access Care Physicians," and "American Access of Staten Island." Dr. Rodino and Dr. Tarantini saw AG at two offices, located at 256 Mason Avenue (3rd Floor) and at 2025 Richmond Avenue in Staten Island, New York.

167. Even after her fistula was matured and dialysis could proceed effectively, Defendants scheduled her for a "follow-up" appointment on October 24, 2012. The pretext for this unnecessary appointment as recorded on patient records created by Defendants was "to reevaluate her fistula."

168. There was no reason for Defendants to see AG again in October 2012 to "reevaluate her fistula" because AG was currently undergoing dialysis by her treating medical staff who monitored her vascular access and dialysis effectiveness on a constant and ongoing basis.

169. Despite the fact that Defendants had self-referred AG for her October 2012 appointment, the patient record created by Defendants for that appointment falsely listed Matthew Palombini, M.D. as the "Referring Physician."

170. At the October 2012 appointment, the patient records created by Defendants indicate that Defendants' employee observed "some pulsatility" in the fistula.

171. As explained earlier, this is precisely the type of non-quantitative, subjective visual assessment that must be corroborated by the results of other monitoring tests before jumping to the conclusion that the patient's ability to receive dialysis has been impaired and that performing a procedure to intervene in a patient's vascular system is reasonable and necessary.

172. Nonetheless, based on that observation alone, Defendants performed "serial fistulagrams" on AG at this visit. The patient records created by Defendants indicate the results of the fistulagrams were that an 80% stenosis and a 60% stenosis were observed.

173. According to professional guidelines, in order for a stenosis to be "hemodynamically significant," it must involve greater than 50% narrowing and be accompanied by other clinical indicia.

174. On the basis of the fistulagram alone, Defendants then performed two angioplasties on AG.

175. Tellingly, AG had undergone dialysis treatment one day prior to this appointment (October 23, 2012) and the blood flow data from that dialysis session did not identify any evidence of fistula dysfunction. Specifically, the clinical measurements taken only one day earlier indicated treatment at the prescribed blood flow rate, with normal arterial and venous pressure, and an excellent rate of toxin removal.

176. In short, AG had successfully undergone dialysis treatment only one day before Defendants subjected her to unnecessary, surgical procedures fraudulently represented to be necessary for her dialysis.

177. If Defendants had simply sought the recent results of vascular access monitoring for this patient from her dialysis center, or asked AG's treating physician for those results, they would have quickly learned that AG's dialysis was proceeding effectively and there was no need for vascular intervention.

178. At the conclusion of AG's October 2012 appointment, Defendants again scheduled her for a follow-up visit in three months. The recorded justification for the follow-up was simply, "for repeat evaluation."

179. AG was next seen by Defendants on January 23, 2013, and was again given a fistulagram and again scheduled for a follow-up visit in three months.

180. On April 24, 2013, AG was again seen by Defendants and again her patient records indicate that "a decreased thrill suspicious for inflow stenosis" was observed by Defendants at that visit.

181. Any "suspicions" of functionally significant stenosis that Defendants may have had should have been immediately quelled by reference to AG's dialysis blood flow data sheets from one day earlier (April 23, 2013), which indicated that hemodialysis was performed at the prescribed blood flow with normal arterial and venous pressures. Additionally, AG's most recent report from her treating nurse just two weeks earlier (April 11, 2013) showed excellent waste removal measures, demonstrating the effectiveness of her dialysis.

182. Despite never bothering to reach out to the patient's treating physician or dialysis center, and despite the absence of corroborating indications that the patient's ability to successfully undergo dialysis was in any way compromised, Defendants again performed an unnecessary fistulagram and angioplasty in April 2013, and again scheduled AG for yet another visit in three months.

183. Defendants' patient records state that the result of these procedures was that "her fistula may be utilized at this time." As AG's fistula was successfully used for dialysis just one day prior, this statement demonstrates that Defendants' procedures were entirely unnecessary.

184. The patient report created by Defendants following AG's April 2013 examination indicated that the follow-up was scheduled to "evaluate for recurrent stenosis." This asserted justification was false since AG was already being monitored on a constant basis by her treating medical staff for any impairment to her dialysis. Further, the use of such evaluations simply to screen patients for possible evidence of a problem is not reimbursable under Medicare guidelines.

185. Again, the patient report created by Defendants following AG's April 2013 procedure falsely listed Dr. Palombini as the "Referring Physician," and ended with "Thank you for the referral." Dr. Palombini, a nephrologist and the patient's treating physician, did not refer AG for these medically unnecessary procedures.

186. Defendants saw AG again on July 24, 2013, again claimed to have observed "mild pulsatility", again performed an unnecessary fistulagram on that basis alone, and again performed an angioplasty after purportedly observing a 60-70% stenosis. As with her earlier procedures, AG had undergone successful dialysis treatment the day before and the documented results of monitoring tests performed that day indicate normal fistula functioning and no dialysis impairment.

187. As with the previous visit, Defendants' patient record states that "[t]he patient may resume use of the AV fistula for dialysis immediately," notwithstanding that there was no interruption of her ongoing dialysis.

188. The records created by Defendants regarding AG's July 2013 procedure again falsely indicated that the visit was referred by Dr. Palombini, and again AG was scheduled for another appointment under the fraudulent pretext of "help[ing] maintain patency of her fistula." No "help" was needed, however, as the records from her dialysis treatment indicate that AG's fistula was operating effectively at the time of the July 2013 procedure.

189. The patient was seen by Defendants on October 23, 2013, and the same course of conduct on Defendants' part followed: observation of "diminished thrill," no corroborating indications of functionally significant stenosis, unnecessary fistulagram and angioplasty performed, and records falsified to indicate that the visit was referred by AG's treating physician.

190. On information and belief, Defendants' practice of performing unnecessary procedures on AG which they misrepresented were the result of a referral by her treating physician and which they falsely claimed were medically justified based only on an uncorroborated, subjective finding, continues to this day.

Patient 2 (J.C.)

191. Patient JC is a 54 year-old male who was initially referred to Defendants' facility in July 2012 by his treating physician at the Staten Island Artificial Kidney Center, Dr. Matthew Palombini, for the purpose of "superficializing" (*i.e.*, moving towards the surface of the skin so that it can be accessed during dialysis) his fistula.

192. Both before and after the legitimate procedures, however, Defendant scheduled and performed at least ten unnecessary procedures from July 2012 through February 2014.

193. Specifically, these follow-up appointments and procedures were scheduled and performed by Dr. William Rodino and Dr. Frank Tarantini, both of Verrazano Vascular Associates.

194. Even though a simple visual examination of the fistula site can determine whether it is close enough to the skin surface for dialysis, Defendants performed procedures on July 17, 2012 (angiogram) and July 31, 2012 (ultrasound scan) prior to the surgery to superficialize the fistula on August 13, 2012.

195. After two additional visits that were legitimately indicated for post-surgery examination, Defendant resumed the pattern of unnecessary procedures by scheduling a fistulagram on August 28, 2012 even though a physical exam is sufficient for such examination.

196. At the August 28, 2012 exam, Defendants recorded "some pulsatility" of the fistula as an excuse to perform the unnecessary procedure.

197. In September 2012, the regular monitoring of JC's vascular access during dialysis indicated that clots had formed which were obstructing dialysis function. Accordingly, JC's treating medical staff properly referred him to Defendants for an angioplasty.

198. However, Defendants self-referred an additional appointment on October 10, 2012 to perform a "Duplex scan" (ultrasound) purportedly to determine whether the fistula was working properly. This was a completely unnecessary procedure since JC was currently undergoing dialysis and being monitored clinically on a regular basis.

199. On November 7, 2012, Defendants performed an angiogram on JC purportedly to look for any stenosis. This was again entirely unnecessary and inappropriate since JC was being monitored for dialysis impairment on a regular basis by his treating medical staff, and angiograms are not suitable for surveillance without any clinical indication that vascular access might be impaired.

200. There followed five additional self-referred appointments from November 2012 through November 2013, all finding vague "pulsatility" of the fistula and all resulting in the performance by Defendants of unnecessary angiograms and often angioplasties to address purported stenosis that at no time impaired JC's dialysis effectiveness.

201. Defendants' patient reports for each of these appointments – on November 15, 2012; December 27, 2012; April 16, 2013; July 18, 2013; and November 18, 2013 – falsely indicated that Dr. Palombini had referred JC for the procedure.

202. On information and belief, Defendants' practice of performing unnecessary procedures on JC justified by fraudulent records continues to this day.

Patient 3 (C.L.)

203. Patient CL is a 69 year-old female who began dialysis in November 2012. Following a legitimate procedure referred by her treating physician, Dr. Kiroycheva, to address clotting, CL resumed dialysis with no problems but was self-referred by Defendants for a number of unnecessary procedures from December 2012 through November 2013.

204. Specifically, these follow-up appointments and procedures were scheduled and performed by Dr. William Rodino of Verrazano Vascular Associates.

205. CL was seen by Defendants for a self-referred appointment on December 27, 2012. The patient record created by Defendants for this appointment falsely indicated that CL was referred for that visit by her treating physician.

206. At the December 27, 2012 appointment, the patient records created by Defendants indicated that CL had a "pulsatile" fistula.

207. The day before, on December 26, 2012, CL had received her most recent dialysis treatment, documented monitoring results from which indicated normal blood flow and venous pressures and no indication of any impairment of dialysis.

208. In addition, CL's most recent monthly laboratory report found excellent vascular clearance and waste removal measures, consistent with properly functioning dialysis.

209. In reckless disregard of documented tests showing effective dialysis treatment, Defendants performed an unnecessary fistulagram and angioplasty on CL on December 26, 2012.

210. Defendants self-referred CL for a follow up in three months, without any documented reason for scheduling that appointment.

211. CL was next seen by Defendants on May 16, 2013 and the patient record created by Defendants for that visit again falsely indicated that CL was referred by Dr. Kiroycheva.

212. The "exam" again found a "pulsatile" fistula and again Defendants performed a fistulagram and angioplasty to address a purported 70-80% stenosis.

213. The day before, on May 15, 2013, CL had received her most recent dialysis treatment, the documented monitoring results from which again indicated dialysis was performed at the prescribed blood flow rate with venous pressures showing no indication of any impairment of dialysis delivery or fistula function.

214. The most recent monthly note from CL's treating nurse was dated only two weeks prior (April 29, 2013) and reported excellent clearances and waste removal metrics, and contained no suggestion of fistula dysfunction.

215. In apparent reference to the standard that vascular intervention should only be performed on stenoses that are "hemodynamically significant," the patient report created by Defendants for the May 15, 2013 visit noted that after the procedure "[t]he patient's fistula is less pulsatile, and may be used for hemodialysis at this time." This notation highlights the fraudulent nature of Defendants' actions, since CL had just undergone successful hemodialysis one day before this procedure.

216. CL was scheduled by Defendants for another appointment in three months.

217. At her next unnecessary appointment on August 15, 2013, the process was repeated: CL was seen by Defendants, patient records were falsified to indicate that CL's treating physician had referred her for this visit, and a "pulsatile" fistula was cited to justify an angiogram notwithstanding that CL had undergone successful dialysis just the day before.

218. CL was scheduled by Defendants for another appointment in three months.

219. At her November 14, 2013 appointment, Defendants continued their practice of fraudulently performing unnecessary fistulagrams and angioplasties on CL's purported "pulsatile" fistula. Again this was done despite CL's successful dialysis and related monitoring tests just one day earlier, and in the absence of a referral from her treating physician.

220. On information and belief, Defendants' practice of performing unnecessary procedures on CL justified by fraudulent records continues to this day.

Patient 4 (A.L.)

221. Patient AL is an 81 year-old male on dialysis treatment. AL was never referred by his treating medical staff to Defendants for a procedure. AL was under the care of his treating physician, Dr. John Pepe.

222. Appointments and procedures were scheduled and performed on AL by Defendants, specifically by Dr. Abigail Falk, Dr. William Rodino and Dr. Frank Tarantini, of Verrazano Vascular Associates.

223. On March 22, 2012, AL visited Defendants' clinic and was seen for an examination. Defendants' patient records for this visit state, "consultation requested by referring nephrologist," which was false.

224. The patient record created by Defendants for this visit indicates that AL had a "pulsatile" fistula and stated that "a fistulagram was indicated" on that basis.

225. Defendants performed a fistulagram on AL at the March 2012 appointment and scheduled him for a follow-up in six months.

226. The recorded justification for this "follow-up" was "routine surveillance."

227. Consistent with professional standards of practice, AL already was under "routine surveillance" by his team of treating dialysis staff.

228. AL was seen in a series of self-referred appointments at Defendants' clinic – on September 27, 2012; January 17, 2013; May 30, 2013; and September 26, 2013 – and invariably Defendants' interventionalist purportedly observed a "pulsatile" fistula and performed a fistulagram and angioplasty.

229. The patient report created by Defendants for the January 17, 2013 procedure states that "[t]he patient may resume use of his fistula for dialysis immediately and will require a follow-up evaluation in four months." There was no indication prior to the procedure performed at this appointment that AL's dialysis was ineffective, nor did Defendants provide any justification for a follow-up visit.

230. On information and belief, Defendants' practice of performing unnecessary procedures on AL justified by fraudulent records continues to this day.

Patient 5 (P.B.)

231. Patient PB is a 66 year-old female with ESRD under the care of her treating physician, Dr. Palombini. From at least as early as December 2013, PB was self-referred by Defendants for a number of unnecessary procedures continuing to the present day.

232. Defendants saw PB on at least six occasions since December 2013, and during those visits performed numerous fistulagrams that invariably resulted in angioplasties. These procedures were performed by Frank Tarantini and William Rodino of Verrazano Vascular Associates.

233. PB was subjected to a fistulagram and angioplasty on December 12, 2014 and instructed to return for yet another appointment in three months.

234. However, on December 24, 2014, PB's Medicare Advantage insurer, Touchstone Health, issued a Notice of Denial of Medical Coverage for additional "routine follow up" visits and "potential interventions for the fistula," for lack of medical necessity.

235. Touchstone Health justified its determination that a "routine follow up" and intervention on her fistula were not medically necessary by the absence of "reports that you are currently having inadequate or problematic dialysis" from her dialysis center.

236. The Notice of Denial of Medical Coverage informed PB that coverage might obtain in the future if she developed problems with her dialysis and was referred to a vascular surgeon by her dialysis center.

237. On information and belief, Defendants' practice of performing unnecessary procedures on PB justified by fraudulent records continues to this day.

Patient 6 (J.F.)

238. Patient JF is a 31 year old female with ESRD under the care of her treating nephrologist, Dr. Richard Sherman. Dr. Sherman referred JF to an FVC facility in Union, NJ called "Access Care Physicians of NJ" when she encountered problems with her dialysis. Thereafter, Defendants self-referred numerous "follow-up" appointments with JF in 2013.

239. JF was seen at Defendants' facility in April 2013, at which time she received multiple angioplasties. Following those procedures, Defendants self-referred a follow-up visit in three months.

240. JF was next seen by Defendants on July 15, 2013. At that time, Defendants recorded that her fistula was "highly pulsatile" and performed a fistulagram. Defendants recorded observing a 70% stenosis and performed an angioplasty on JF. Defendants scheduled JF for yet another follow-up appointment in three months.

241. On October 2, 2013, JF was again seen by Defendants, who again recorded a "pulsatile" fistula, performed a fistulagram, recorded a stenosis greater than 70%, and performed an angioplasty. Defendants' records for this patient indicate that another appointment was scheduled "in three to four months for routine maintenance."

242. However, just two weeks prior to Defendants' October 2, 2013 unnecessary procedures, JF was given a series of tests at her dialysis facility. All of these tests indicated that her dialysis was performing adequately. Patient records from JF's dialysis facility on September 17, 2013 state that "[t]he findings [of the dialysis center's monitoring tests] are consistent with a normal access or the presence of anatomic lesions which are currently functionally insignificant."

243. The FVC physician who performed these unnecessary procedures on JF was Dr. Walead Latif.

D. Additional Allegations of Scienter

244. As the world's largest provider of dialysis services and products, Defendant Fresenius is uniquely positioned to understand the laws and professional standards applicable to all aspects of ESRD patient treatment, including the specific role of vascular access clinics in the broader context of patient care.

245. Fresenius is one of the world's largest dialysis clinic operators and therefore is well aware that under Medicare, the responsibility for monitoring dialysis access lies with the dialysis center, not with outside vascular interventionalists, and that payment for monitoring is included within the composite reimbursement rate for treating an ESRD patient.

246. Moreover, Fresenius has ample reason to recognize that repeat periodic surveillance fistulagrams and angioplasties are not just medically unnecessary, they also pose a

risk of physically harming the ESRD patient. Indeed, three physicians from Fresenius' Clinical Research Division published a study in November 2011 (just after Fresenius's acquisition of American Access Care) addressing the effectiveness and proper role of fistulagrams and angioplasties on dialysis patients. This large scale study, published in the Clinical Journal of the American Society of Nephrology and available on the Internet, stated that:

- A review of over 35,000 Medicare beneficiaries from 2004-2007, primarily sourced from Fresenius dialysis clinics, found no difference in vascular access survival between those who received "preventative" or "elective" angioplasties and those that did not.
- The only patients who benefitted from these angioplasties were those with relatively new fistulas (< three months old), had low blood flow rates or low Kt/V clinical measures.
- In contrast, all other patient groups saw preventative angioplasties associated with decreased access survival – a conclusion consistent with the fact that interventional procedures themselves cause damage to blood vessels and create new stenoses.
- Preventative angioplasties were also associated with the risk (>1%) of certain "serious adverse events," which rate did not include the further incidence of harm to residual kidney function caused by contrast dye.

Chan et al., "Access Survival amongst Hemodialysis Patients Referred for Preventive Angiography and Percutaneous Transluminal Angioplasty," Clin. J. Am. Soc. Nephrol. (Nov. 2011).

247. This study also acknowledged that the decision of whether and when a dialysis patient should receive an access intervention was in the discretion of the attending physician at the dialysis center. Indeed, the title of the article indicates Fresenius' awareness that patients must be "referred for" these services.

248. The data used for this study indicated an overall rate of angioplasties of 20.9 per 100 patient access-years (or around one procedure per patient every five years). The study described this rate as "frequent" and "commonly done." In comparison, Fresenius self-refers patients for follow-up appointments approximately every three to four months, which equates to up to four procedures per patient per year – or 20 times more frequently than in the study data.

249. In recent years, the Department of Justice has successfully taken legal action against vascular interventionalists for violations of the federal False Claims Act arising from subjecting dialysis patients to unnecessary fistulagrams and angioplasties.

(a) On July 2, 2015, the Department of Justice announced that it had settled a false claims act case against American Access Care[3] for billing Medicare for unnecessary angioplasties performed on dialysis patients at its Miami facility prior to being acquired by Fresenius. The press release noted that "Patients at the facility were routinely brought back for follow-up visits that were not justified by the patients' condition."

(b) On May 6, 2015, the Department of Justice announced that it had settled a false claims act case against a vascular access company in New York City, Mattoo & Bhat Medical Associates, P.C. ("AV Care"). The DOJ explained: "As a regular practice, AV Care routinely scheduled patients for fistulagrams and

[3] As described in ¶¶ 26-29, Fresenius purchased American Access Care in 2011.

angioplasties as many as three months in advance, and [its] surgeons … performed these fistulagrams as a matter of routine even if the patient presented without a clinical reason." Further, the release noted, angioplasties were performed when the patient information and records did not support the presence of a restriction in the blood vessel of over 50%.

(c) On September 28, 2015, the Department of Justice announced that it had settled two additional false claims act cases against American Access Care facilities, one located in Rhode Island and the second located in Connecticut for, among other unlawful conduct, submitting claims to Medicare and Medicaid for procedures performed during dialysis patient follow up visits which were not medically necessary, prior to being acquired by Fresenius.

(d) On December 3, 2018, the Department of Justice announced that a vascular surgeon also named as a defendant in the AV Care false claims matter, who had contributed personally to the settlement, had been indicted and arrested for opening up his own surgical practice after the 2015 settlement and engaging in the same unlawful conduct again.

250. On its website, Fresenius Vascular Care discloses the fact that it oversees on a chain-wide basis numerous operational and administrative functions of its clinics. In particular, it showcases the fact that it has responsibility for ensuring that all Fresenius Vascular Care clinics are in compliance with all local, state and federal requirements. Thus Fresenius Vascular Care holds itself out as knowledgeable regarding applicable statutory and regulatory requirements for Medicare and Medicaid billing and moreover, as responsible for ensuring that all its clinics adhere to them.

251. The following allegations, among others, demonstrate Defendants' knowledge that its patient records indicating that follow-up appointments were referred by a patient's treating physician were false, as were the submissions to Medicare and Medicaid for their payment:

(a) Defendants' interventionalists that conducted the unnecessary procedures filled out patient records indicating referrals from the treating physician even though the interventionalists knew first-hand that the patient was self-referred by Defendants.

(b) Defendants were aware of Medicare laws and regulations requiring that billed diagnostic procedures be performed only at the request of the treating physician. Defendants stated in their Code of Conduct that providing "superior clinical care to [its] patients" required that "[c]linical care must be based on patient medical needs and physician orders." (Emphasis added.)

(c) Further, Defendants acknowledged their responsibility to inform their employees of applicable laws in their Code of Conduct, which stated that Defendants "provide general Compliance training for all personnel" and give "more focused compliance training tailored to the issues and challenges" of each business segment, including vascular care.

252. The following allegations, among others, demonstrate Defendants' knowledge that repetitive intervention procedures based only on purported physical observation of a patient's vascular access site were insufficient to demonstrate medical necessity and justify Medicare reimbursement:

(a) Defendants were aware of Medicare laws and guidance requiring that billed procedures be "reasonable and necessary for the treatment" of patients.

(b) Defendants were aware of the professional standards contained in the KDOQI Guidelines requiring that physical observation of possible stenosis should be confirmed with a corroborating clinical test to determine if the stenosis is "hemodynamically significant."

(c) Defendants were aware that patients were undergoing comprehensive access monitoring as required as part of their regular dialysis treatment. Fresenius itself operates the largest network of dialysis clinics in the U.S., administers dialysis treatment to over 270,000 patients across the globe, and describes on its website the type of clinical monitoring that it performs on a regular basis for its own dialysis patients.[4] Nevertheless, Fresenius self-refers patients for repeat follow-up fistulagrams and angioplasties but does so without a referral and without asking for, or having the benefit of, the critical clinical observations regarding dialysis function, such as the Kt/V ratio, available from the patient's dialysis center.

253. Defendants' Code of Conduct asserts its compliance with applicable laws, including the False Claims Act, and acknowledged as violations of such laws the illegal practices of "[b]illing for medically unnecessary services," "[c]haracterizing non-covered services or costs in a way that secures reimbursement," and "[o]ffering, providing or receiving kickbacks," such as free meals and transportation to patients.

[4] http://www.ultracare-dialysis.com/Treatment/InCenterDialysis/MonitoringYourCare.aspx (last visited May 28, 2014).

254. Fresenius acknowledged the need to comply with Medicare and other federal and state laws when it entered into a Corporate Integrity Agreement ("CIA") in 2000 as part of a settlement in which it paid $486 million to the United States to resolve claims that it engaged in a conspiracy to defraud Medicare and other government health benefit organizations.

255. Specifically, Fresenius pleaded guilty to criminal conspiracy charges and settled related False Claims Act whistleblower litigation regarding its scheme to defraud the Government by, among other things, submitting false claims for reimbursement for dialysis-related treatments that were not medically necessary.

256. The CIA required Defendant Fresenius Medical Care North America to maintain a comprehensive compliance program headed by a Corporate Compliance Officer and Corporate Compliance Committee, and a Code of Ethics and Business Conduct that documents its commitment to compliance with federal laws and reimbursement policies.

257. The CIA also addressed substantive issues with Defendants' business operations, requiring, among other things, that Defendants cease billing the Government for laboratory tests and services that are not medically necessary, institute practices to ensure that forms requesting tests and diagnostic procedures are signed by the ordering physician, and that Defendants establish internal controls to prevent the submission of claims that lack medical necessity to the Government.

258. Since entering into the CIA, Fresenius has continued to bill the Government for ESRD-related treatments that were not medically necessary and/or not ordered by a patient's treating physician.

259. In 2010, the OIG found that Fresenius's ESRD laboratory unit was performing medically unnecessary tests as well as tests that were not ordered by the treating physician, and recommended that Fresenius refund $5.4 million to the Government.

260. In its 2010 Report, the OIG specifically addressed an example where a patient was validly referred by a physician for a single test but Fresenius performed three tests on that patient. The OIG determined that because the two subsequent tests were not ordered by the treating physician, they were not reasonable and necessary.

261. Accordingly, Defendants were aware at all relevant times that their fraudulent practices described herein violated Medicare and Medicaid requirements and that the reimbursement they received for those services constituted "overpayments" that should have been returned to the government.

E. The Extent Of Defendants' Fraudulent Scheme And Harm To The Government

262. In the course of their treatment of ESRD patients who have been and continue to be subject to Defendants' unnecessary procedures, Relators have acquired documents from Defendants that summarize the vascular access procedures Defendants have performed on Relators' patients and the purported justification for each.

263. These documents also falsely indicate that every procedure had a referring physician, and list "referral reasons" for each procedure, even though the majority was self-referred for no valid reason at all.

264. Defendants' documents indicate for each procedure one of eleven supposed justifications, such as "clotted" or "suture removal." Procedures that were self-referred without medical justification were categorized vaguely as "Evaluation" or "Eval & Treat."

265. According to Defendants' own documents in the possession of Relators, in a 10-month period in 2013, Defendants performed approximately 249 procedures on patients from the Carol Molinaro Dialysis Center.

266. Based on Relators' review of these documents and their professional experience, approximately 89 of these procedures were legitimately referred by treating medical staff at the Carol Molinaro Dialysis Center and were accordingly categorized with one of the ten justifications other than "Evaluation."

267. The rest, about 160 or 64% of these procedures, were the result of Defendants' fraudulent practice of self-referral.

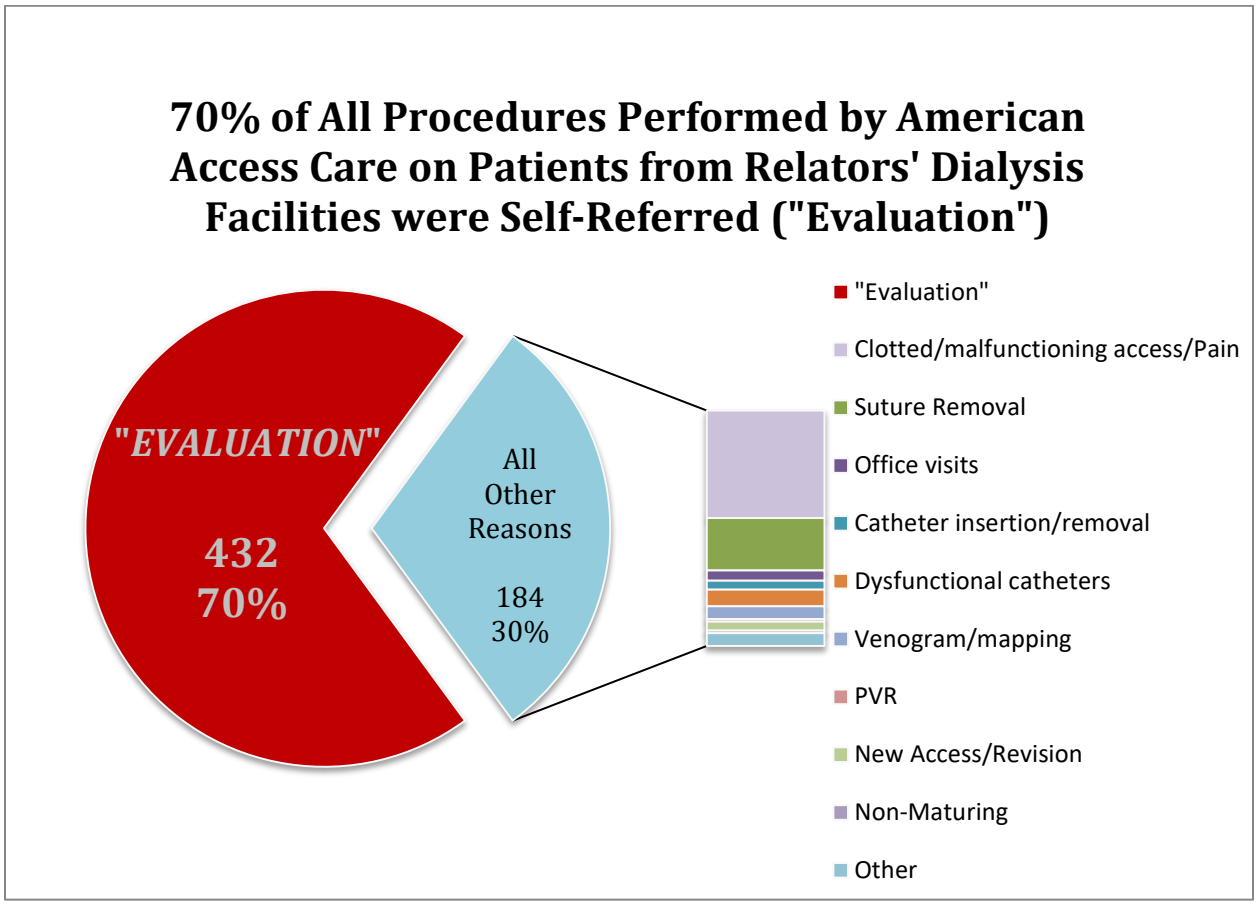
268. According to Defendants' own documents in the possession of Relators, in an 11-month period in 2013, Defendants performed approximately 367 procedures on patients from the Staten Island Artificial Kidney Center.

269. Based on Relators' review of these documents and their professional experience, approximately 95 of these procedures were legitimately referred by treating medical staff at the Staten Island Artificial Kidney Center and were accordingly categorized with one of the ten justifications other than "Evaluation."

270. The rest, about 272 or 74% of these procedures, were the result of Defendants' fraudulent practice of self-referral.

271. Together, these figures – from Defendants' own documents – show that 70% of all procedures Defendants performed on patients from Relators' dialysis facilities were fraudulently self-referred.

272. The chart below illustrates the magnitude of Defendants' fraud, and demonstrates that self-referred procedures for "Evaluation" comprise the overwhelming majority of all procedures performed for any reason.



273. On information and belief, the average reimbursement for the types of vascular intervention procedures fraudulently and unnecessarily performed by Defendants is approximately $2,500.00.

274. At a rate of $2,500.00 per procedure, Defendants' documents covering patients receiving dialysis at just two New York facilities indicate over $1 million in fraudulent reimbursements within a 10-11 month timeframe.

275. These figures only address patients initially referred from two facilities to a single FVC clinic in a time period of less than one year. Each Fresenius Vascular Care clinic performs procedures on patients initially referred from many facilities, and Fresenius has well over 60 clinics nationwide. Accordingly, the potential harm to the Government from Defendant's multi-year fraud is easily in the hundreds of millions of dollars.

F. Defendants' Nationwide Practices of Performing Medically Unnecessary Procedures For Which They Fraudulently Obtained Government Payment

276. The specific fraudulent practices described in this Complaint are not limited to the particular Defendant facilities detailed herein, or even to the States of New York and New Jersey. Recently released Medicare Part B payment data demonstrates that Defendants' practices of performing medically unnecessary procedures for which they fraudulently obtained Government payment is nationwide.

277. Medicare Part B payment data for 2012 through 2014 has been aggregated on the website Propublica.org, in a feature called "Treatment Tracker"[5] that provides by individual physician, among other metrics, the number of Medicare services performed, the average services per patient, and the total dollars received by Medicare, as well as "ranks" by specialty and state.[6]

278. Gregg Miller, the Chief Medical Officer of Fresenius Vascular Care and a practicing physician, performed 127,972 "services" on patients in 2012, which ranked him number one out of 221 physicians in the State of New York practicing in the "Critical Care (Intensivists)" specialty. He averaged 193.6 services per patient, which was in the top 10% for

[5] http://projects.propublica.org/treatment (last visited May 28, 2014).

[6] The methodology used by Treatment Tracker to calculate its statistics can be viewed at http://www.propublica.org/article/how-we-analyzed-medicare-part-b-data (last visited May 28, 2014).

that metric. Dr. Miller received $4.84 million from Medicare Part B in 2012, which placed him at number one in his specialty in New York.

279. In 2013, during which time Dr. Miller was in the executive position of Chief Medical Officer, he nonetheless performed over 24,000 services and was again in the top 10% for services per patient. He received over $1.2 million from Medicare Part B in 2013, which was fifth out of six hundred and fifty providers in the "Nephrology" specialty in New York.

280. In 2014, during which time Dr. Miller remained in the executive position of Chief Medical Officer, he performed over 9,500 services and remained in the top 10% for services per patient. He received nearly $450,000 from Medicare Part B in 2014, which was in the top 10% of providers in the "Nephrology" specialty in New York.

281. Frank Tarantini, one of the physicians at Defendants' facility on Staten Island, performed 27,956 "services" on patients in 2012, which placed him at number two out of 1,282 physicians in the State of New York practicing in the "General Surgery" specialty. He averaged 69.9 services per patient, which was in the top 10% for that metric. Dr. Tarantini received $1,510,000 from Medicare Part B in 2012, which placed him at number three among 1,282 "General Surgery" physicians in New York.

282. Dr. Tarantini similarly received $1.6 million from Medicare Part B in 2013, which was third-highest within the "Vascular Surgery" specialty in New York.

283. Dr. Tarantini received $2.15 million from Medicare Part B in 2014, which was second-highest with the "Vascular Surgery" specialty in New York.

284. William Rodino, another physician at Defendants' facility on Staten Island, performed 19,016 services in 2012, which ranked number three out of 248 physicians in the State of New York practicing in the specialty of "Vascular Surgery." He averaged 57.5 services per

patient, which was in the top 10% for that metric. Dr. Rodino received $923,000 from Medicare Part B in 2012, which ranked number ten among 248 "Vascular Surgery" physicians in New York.

285. Dr. Rodino similarly received nearly $1.5 million from Medicare Part B in 2013, fourth-highest (immediately behind Dr. Tarantini) among New York vascular surgeons.

286. Dr. Rodino received $1.37 million from Medicare Part B in 2014, which ranked eighth-highest among New York vascular surgeons.

287. Walead Latif, a physician at Defendants' facility in Union, New Jersey, performed 78,081 services in 2012, which ranked number four out of 3,394 physicians in the State of New Jersey practicing the specialty of "Internal Medicine." He averaged 118.7 services per patient, which was in the top 10% for that metric. Dr. Latif received $3.69 million from Medicare Part B in 2012, which ranked number one among the 3,394 "Internal Medicine" physicians in New Jersey.

288. Dr. Latif similarly received $3.95 million from Medicare Part B in 2013, performing the single highest number of services and receiving the most Medicare revenue out of 288 providers in the "Nephrology" specialty in New Jersey.

289. Dr. Latif received $3.34 million from Medicare Part B in 2014, again performing the single highest number of services and receiving the most Medicare revenue out of 286 providers in the "Nephrology" specialty in New Jersey.

290. Drs. Miller, Tarantini, Rodino, and Latif were in no way outliers among Fresenius Vascular Care practitioners. Treatment Tracker provides data for 38 of the 42 physicians currently listed on Fresenius Vascular Care's website, who received in total over $75 million

from Medicare Part B in 2012.[7] Of those 38 Fresenius Vascular Care physicians, 28 ranked in the top 30 total physicians for services performed in their respective state and specialty. Likewise, an exceptionally large number – ten – of those Fresenius Vascular Care physicians were the single largest provider of Medicare services in their respective state and specialty.

291. Of those 38 Fresenius Vascular Care physicians, 29 ranked in the top 30 total physicians for dollars received from Medicare in their respective state and specialty in 2012. Thirteen of those Fresenius Vascular Care physicians were the single largest recipient of Medicare dollars in their respective state and specialty.

292. The extremely high numbers of services performed and Medicare dollars received were not due simply to an abnormally high number of patients treated. Indeed, 28 of the 38 Fresenius Vascular Care physicians for whom 2012 data was available ranked in the top 10% in the metric of "services per patient" in their respective state and specialty.

293. These figures only increased in 2013, when Fresenius Vascular Care physicians received over $82 million from Medicare Part B.

294. Fresenius Vascular Care physicians received over $148 million from Medicare Part B in 2014.[8]

295. By any measure, the payment data for the FVC physicians listed in Treatment Tracker is extraordinary. There are almost uniformly high numbers for the amount of services and Medicare Part B reimbursement amounts attributable to FVC physicians company-wide from 2012 to 2014, strongly suggesting that something beyond mere chance is at work. Rather, they indicate that Defendants seek to increase their billing beyond medically justifiable levels by

[7] *See* http://freseniusvascularcare.com/about-physicians.php (last visited May 28, 2014).

[8] Attached as Exhibit 1 to this Third Amended Complaint is a chart created by Relators that contains Medicare Part B payment information for the physicians employed by Fresenius Vascular Care in 2014.

performing repetitive and unnecessary fistulagrams and angioplasties on a susceptible patient population.

296. Since the first half of 2011, Fresenius has been engaged in providing individual Fresenius executives, independent nephrologists and both Fresenius Vascular Care and other vascular interventionalists with an ownership and/or management interest with respect to Fresenius Vascular Clinics. Specifically, at least 23 Fresenius Vascular Access Clinics "FVACs" have been organized as LLCs and have issued equity securities pursuant to Rule 506(b) of Regulation D under Section 4(a)(2) of the Securities Act. They are located throughout the United States, in locales such as North Carolina, Wisconsin, Texas, Florida, Massachusetts and California.

297. Rule 506(b) is one of the "safe harbor" exemptions which allow a company to raise money by issuing securities which are exempt from SEC registration requirements. The securities investors receive are restricted, meaning that they cannot be sold for at least a year without registering them. Although registration of the securities is not required, a Form D must be filed with the SEC giving basic information regarding the amount of money invested and identifying the officers of the company.

298. As the Form D's indicate, for each of these FVC facilities, the directors and managers of the LLC include several Fresenius corporate executives. For 8 facilities, including facilities in Massachusetts, Kentucky, North Carolina, South Carolina, Alabama, Florida, and California, these executives include Gregg Miller. Many also include Joseph Ruma, Vice President of Business Development for Fresenius Medical Care, N.A. Each offering also identifies as directors and/or managers one or more physicians. These physicians are either (a) FVC interventionalists that work at the facility, (b) local interventionalists unaffiliated with FVC,

or (c) local nephrologists (at non-Fresenius dialysis centers) that provide dialysis services. This fact raises the specter that Fresenius has provided these physicians with an ownership or other financial interest in the FVC facility which effectively incentivizes them to refer ESRD patients for repeat fistulagrams and angioplasties which are neither reasonable nor necessary but very lucrative to FVC and to the physicians.

G. Defendants Continued Their Fraudulent Practice Of Self-Referring And Performing Medically Unnecessary And Non-Covered Vascular Intervention Procedures During The Coronavirus Pandemic By Falsely Representing Them As Emergency Services

299. In response to the coronavirus pandemic, many if not all states implemented restrictions on the types of medical procedures that could be performed in order to protect patients and conserve healthcare resources for the treatment of those most seriously ill.

300. These restrictions typically took the form of a prohibition on all "elective" procedures for certain periods of time. For example, an Executive Order issued by the Governor of New York on March 23, 2020 (EO No. 202.10) directed "all general hospitals, ambulatory surgery centers, office-based surgery practices and diagnostic and treatment centers to increase the number of beds available to patients, including by canceling all elective surgeries and procedures…."

301. In order to ensure that the most critically ill patients were still able to receive life-saving treatment, these restrictions did not prohibit medical services that were truly needed for emergency care.

302. Faced with the loss of revenue that would be caused by a cessation of their medically unnecessary vascular intervention procedures were they to comply with these state restrictions, Defendants instead announced that they would continue performing these procedures based on their "belief" that they were "not elective."

303. On March 30, 2020, Fresenius issued a "Global Medical Advisory" to its "Worldwide Employees, Providers, Affiliates and Patients" regarding what it referred to as "Apportioning Care During the COVID-19 Pandemic Period."

304. This advisory began with an acknowledgement that "The SARS-COV2 Coronavirus has led to a pandemic of COVID-19 disease that has spread throughout the world creating social, economic and health care impact [sic] on most people's daily lives," and that as a result, "[r]esource constraints are leading to decisions and discussions regarding access to critical health services for people infected with the virus and in need of care."

305. Nevertheless, Fresenius stated among its "Statement of Medical Principles" that "[d]espite the surge in viral infections disease due to COVID-19 … During this time patients with ESKD may need dialysis access surgery or interventions. ***We believe these are not elective procedures*** and should be delivered in a timely manner to avoid additional exposure to central venous catheters that can lead to additional known complications." (Emphasis added.)

306. Following this global directive, Azura issued a public letter to its patients in April 2020 that described certain safety protocols at its centers but made no mention of its "belief" that interventional vascular access procedures were "not elective" or that it would evaluate whether *any* appointments for clinically timed evaluations were not necessary given the important state restrictions in place across the country.

307. Defendants' contravention of state orders designed to protect patients and conserve healthcare resources during the coronavirus pandemic acted to sustain its flow of revenues during a period of time when the financial position of many healthcare companies has suffered because revenues have dropped.

308. Fresenius's June 9, 2020 presentation at the Goldman Sachs Healthcare Conference touted its "Positive Q1 earnings growth despite impact from COVID-19 pandemic." Fresenius reported 9% quarter-over-quarter revenue growth overall across its North America Health Care Services business, including 9% revenue growth in Care Coordination specifically. Its strong financial performance in 2020 has allowed it to complete a massive stock buyback program (€ 930 million) and propose its 23rd consecutive dividend increase for the 2019 year.

H. Statements And Claims To Medicare And Medicaid For Payment of ESRD Treatment

309. Defendants' fraudulent claims to Medicare Part B were submitted on CMS Form 1450 (UB-04) ("Form 1450"), and were signed by an agent or representative of the Defendants. Upon information and belief, and in accordance with common industry practice, Defendants electronically submitted a claim for payment each time a patient received one or more services or underwent a procedure at an FVC clinic.

310. Defendants' fraudulent claims to Medicaid were submitted on Form 1450, and were signed by an agent or representative of the Defendants. Upon information and belief, and in accordance with common industry practice, Defendants electronically submitted a claim for payment each time a patient received one or more services or underwent a procedure at an FVC clinic.

311. In submitting Form 1450, the provider expressly certifies, among other things, that:

- The billing information as shown on the form is true, accurate and complete; and
- the information submitted as part of this claim is true, accurate and complete, and,
- the services shown on this form were medically indicated and necessary for the health of the patient.

I. Statements And Claims To Commercial Insurance Companies

312. Defendants' fraudulent scheme also caused financial harm to commercial insurance companies that paid Fresenius for medically unnecessary and non-covered vascular access procedures.

313. Private insurance plans offered by commercial insurance companies typically rely on the same standards as Medicare for determining the medical necessity of healthcare services.

314. While Medicare covers a wide range of ESRD services, commercial insurance companies also provide important and costly coverage for ESRD patients under a variety of circumstances.

315. Private insurance plans will cover ESRD services such as vascular access procedures in the following situations, among others:

(a) When a beneficiary is initially diagnosed with ESRD, private insurance will cover all treatment during the 3-month "waiting period" before Medicare coverage applies.

(b) After Medicare coverage begins in the fourth month following ESRD treatment, private insurance will continue to cover certain services during a longer 30-month "coordination period," during which Medicare is generally responsible as a secondary payer.

(c) Even after Medicare becomes the primary payer for a patient with ESRD, private insurance will cover the patient's 20% copayment for Medicare Part B services such as vascular access procedures.

(d) Private insurance may also cover the full costs of certain procedures that are not covered at all by Medicare.

316. In addition, patients with ESRD may be able to join a "special needs" plan offered under the Medicare Advantage Program by a commercial insurance company.

317. Defendants have and continue to submit and make false and fraudulent claims and statements to commercial insurance companies for payment of medically unnecessary and non-covered vascular access procedures, and improperly retain such payments, in violation of numerous provisions of the California Insurance Frauds Prevention Act.

XIX. COUNTS

COUNT I
FEDERAL FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(A)

318. Relators hereby incorporate and re-allege each allegation in each of the preceding paragraphs as though fully set forth herein, and further alleges as follows:

319. Defendants, by and through their agents, officers, and employees, knowingly presented, or caused to be presented to Medicare and other federal health care programs false or fraudulent claims for reimbursement of services provided to ESRD Medicare beneficiaries that were not reasonable and necessary, were not clinically appropriate, and were not properly documented. Accordingly, Defendants presented false submissions to the United States for reimbursement of Government expenditures in violation of 31 U.S.C. § 3729(a)(1)(A).

320. In engaging in the conduct alleged above, Defendants acted "knowingly" as that term is defined in 31 U.S.C. § 3729, in that they acted with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information.

321. As a result of Defendants' violations of 31 U.S.C. § 3729(a)(1)(A), the United States has suffered damages in an amount to be determined at trial.

COUNT II
FEDERAL FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(B)

322. Relators hereby incorporate and re-allege each allegation in each of the preceding paragraphs as though fully set forth herein, and further alleges as follows:

323. Defendants, by and through their agents, officers, and employees, knowingly made, used, or caused to be made or used, false records or statements material to claims for reimbursement to Medicare and other federal health care programs for services that were not reasonably and necessary, were not clinically appropriate, and were not properly documented. These false records and statements included false patient reports indicating physician referrals that were not granted, physical examinations that either did not take place and/or were not sufficient to justify the procedures performed, and scheduled "follow-up" appointments for manufactured reasons or no reason at all. Accordingly, Defendants provided false records and statements material to claims for reimbursement of Government expenditures in violation of 31 U.S.C. § 3729(a)(1)(B).

324. In engaging in the conduct alleged above, Defendants acted "knowingly" as that term is defined in 31 U.S.C. § 3729, in that they acted with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information.

325. As a result of Defendants' violations of 31 U.S.C. § 3729(a)(1)(B), the United States has suffered damages in an amount to be determined at trial.

COUNT III
FEDERAL FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(G)

326. Relators hereby incorporate and re-allege each allegation in each of the preceding paragraphs as though fully set forth herein, and further alleges as follows:

327. Defendants, by and through their agents, officers, and employees, knowingly made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease obligations to pay or transmit money or property to the government.

328. In engaging in the conduct alleged above, Defendants acted "knowingly" as that term is defined in 31 U.S.C. § 3729, in that they acted with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information.

329. As a result of Defendants' violations of 31 U.S.C. § 3729(a)(1)(G), the United States has suffered damages in an amount to be determined at trial.

COUNT IV
ILLEGAL KICKBACKS
42 U.S.C. § 1320a-7b(b) and 31 U.S.C. §§ 3729(a)(1)(A)-(B)

330. Relators hereby incorporate and re-allege each allegation in each of the preceding paragraphs as though fully set forth herein, and further alleges as follows:

331. Defendants, by and through their agents, officers, and employees, knowingly and willfully offered or paid remuneration in the form of free limousine transportation to its patients to induce those patients to appear at Defendants' facilities for medically unnecessary procedures for which payment was made in whole or in part by a Government health care program. Defendants thereby violated the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which itself constitutes a violation of the False Claims Act. 42 U.S.C. § 1320a-7b(g).

332. In engaging in the conduct alleged above, Defendants acted "knowingly" as that term is defined in 31 U.S.C. § 3729, in that they acted with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information.

333. As a result of Defendants' violations of 42 U.S.C. § 1320a-7b(b) and 31 U.S.C. §§ 3729(a)(1)(A)-(B), the United States has suffered damages in an amount to be determined at trial.

COUNT V
NEW YORK FALSE CLAIMS ACT
N.Y. State Fin. Law § 189(1)(a)

334. Relators hereby incorporate and re-allege each allegation in each of the preceding paragraphs as though fully set forth herein, and further alleges as follows:

335. Defendants, by and through their agents, officers, and employees, knowingly presented, or caused to be presented to New York State false or fraudulent claims for reimbursement of services provided to Medicaid beneficiaries that were not reasonable and necessary, were not clinically appropriate, and were not properly documented. Accordingly, Defendants presented false submissions to the State of New York for reimbursement of Medicaid expenditures in violation of New York's False Claims Act. N.Y. State Fin. Law § 189(1)(a).

336. In engaging in the conduct alleged above, Defendants acted "knowingly" as that term is defined in N.Y. State Fin. Law § 188, in that they acted with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information.

337. As a result of Defendants' violations of N.Y. State Fin. Law § 189(1)(a), the State of New York has suffered damages in an amount to be determined at trial.

COUNT VI
NEW YORK FALSE CLAIMS ACT
N.Y. State Fin. Law § 189(1)(b)

338. Relators hereby incorporate and re-allege each allegation in each of the preceding paragraphs as though fully set forth herein, and further alleges as follows:

339. Defendants, by and through their agents, officers, and employees, knowingly made, used, or caused to be made or used, false records or statements materials to false or

fraudulent claims paid or approved by New York State for reimbursement of services provided to Medicaid beneficiaries that were not reasonable and necessary, were not clinically appropriate, and were not properly documented. Accordingly, Defendants presented false submissions to the State of New York for reimbursement of Medicaid expenditures in violation of New York's False Claims Act. N.Y. State Fin. Law § 189(1)(b).

340. In engaging in the conduct alleged above, Defendants acted "knowingly" as that term is defined in N.Y. State Fin. Law § 188, in that they acted with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information.

341. As a result of Defendants' violations of N.Y. State Fin. Law § 189(1)(b), the State of New York has suffered damages in an amount to be determined at trial.

COUNT VII
NEW YORK FALSE CLAIMS ACT
N.Y. State Fin. Law § 189(1)(g) and (h)

342. Relators hereby incorporate and re-allege each allegation in each of the preceding paragraphs as though fully set forth herein, and further alleges as follows:

343. Defendants, by and through their agents, officers, and employees, "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money … to the state … [or] knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the state …" in violation of N.Y. State Fin. Law § 189(1)(g) and (h).

344. In engaging in the conduct alleged above, Defendants acted "knowingly" as that term is defined in N.Y. State Fin. Law § 188, in that they acted with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information.

345. As a result of Defendants' violations of N.Y. State Fin. Law § 189(1)(g) and (h), the State of New York has suffered damages in an amount to be determined at trial.

COUNT VIII
ILLEGAL KICKBACKS – NEW YORK
18 N.Y.C.R.R. § 515.2(b) and N.Y. State Fin. Law § 189(1)(a)-(b)

346. Relators hereby incorporate and re-allege each allegation in each of the preceding paragraphs as though fully set forth herein, and further alleges as follows:

347. Defendants, by and through their agents, officers, and employees, knowingly and willfully offered or paid remuneration in the form of free limousine transportation to its Medicaid patients to induce those patients to appear at Defendants' facilities for medically unnecessary procedures for which payment was made in whole or in part by New York State. Defendants thereby violated the New York Anti-Kickback Statute, 18 N.Y.C.R.R. § 515.2(b). Accordingly, Defendants knowingly presented false or fraudulent claims and made false or fraudulent statements material to such claims in violation of the New York State False Claims Act. N.Y. State Fin. Law § 189(1)(a)-(b).

348. In engaging in the conduct alleged above, Defendants acted "knowingly" as that term is defined in N.Y. State Fin. Law § 188, in that they acted with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information.

349. As a result of Defendants' violations of 18 N.Y.C.R.R. § 515.2(b) and N.Y. State Fin. Law § 189(1)(a)-(b), the State of New York has suffered damages in an amount to be determined at trial.

COUNT IX
NEW JERSEY FALSE CLAIMS ACT
N.J.S.A. 2A:32C-3(a)

350. Relators hereby incorporate and re-allege each allegation in each of the preceding paragraphs as though fully set forth herein, and further alleges as follows:

351. Defendants, by and through their agents, officers, and employees, knowingly presented, or caused to be presented to the State of New Jersey false or fraudulent claims for reimbursement of services provided to Medicaid beneficiaries that were not reasonable and necessary, were not clinically appropriate, and were not properly documented. Accordingly, Defendants presented false submissions to the State of New Jersey for reimbursement of Medicaid expenditures in violation of New Jersey's False Claims Act. N.J.S.A. 2A:32C-3(a).

352. In engaging in the conduct alleged above, Defendants acted "knowingly" as that term is defined in N.J.S.A. 2A:32C-2, in that they acted with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information.

353. As a result of Defendants' violations of N.J.S.A. 2A:32C-3(a), the State of New Jersey has suffered damages in an amount to be determined at trial.

COUNT X
NEW JERSEY FALSE CLAIMS ACT
N.J.S.A. 2A:32C-3(b)

354. Relators hereby incorporate and re-allege each allegation in each of the preceding paragraphs as though fully set forth herein, and further alleges as follows:

355. Defendants, by and through their agents, officers, and employees, knowingly made, used, or caused to be made or used false records or statements to get false or fraudulent claims paid or approved by the State of New Jersey. These false or fraudulent claims for reimbursement of services provided to Medicaid beneficiaries were not reasonable and necessary, were not clinically appropriate, and were not properly documented. Accordingly, Defendants made, used, or caused to be made or used false records or statements to get false or fraudulent claims paid or approved by the State of New Jersey for reimbursement of Medicaid expenditures in violation of New Jersey's False Claims Act. N.J.S.A. 2A:32C-3(b).

356. In engaging in the conduct alleged above, Defendants acted "knowingly" as that term is defined in N.J.S.A. 2A:32C-2, in that they acted with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information.

357. As a result of Defendants' violations of N.J.S.A. 2A:32C-3(b), the State of New Jersey has suffered damages in an amount to be determined at trial.

COUNT XI
NEW JERSEY FALSE CLAIMS ACT
N.J.S.A. 2A:32C-3(g)

358. Relators hereby incorporate and re-allege each allegation in each of the preceding paragraphs as though fully set forth herein, and further alleges as follows:

359. Defendants, by and through their agents, officers, and employees, "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money … to the State" in violation of N.J.S.A. 2A:32C-3(g).

360. In engaging in the conduct alleged above, Defendants acted "knowingly" as that term is defined in N.J.S.A. 2A:32C-2, in that they acted with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information.

361. As a result of Defendants' violations of N.J.S.A. 2A:32C-3(g), the State of New Jersey has suffered damages in an amount to be determined at trial.

COUNT XII
CALIFORNIA FALSE CLAIMS ACT
CAL. GOV'T CODE §§ 12651(a)(1), (2), (7) & (8)

362. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

363. By virtue of the acts described above, Defendants "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Cal. Gov't Code § 12651(a)(1).

364. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Cal. Gov't Code § 12651(a)(2).

365. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state or to any political subdivision, or knowingly conceal[ed] or knowingly and improperly avoid[ed], or decrease[d] an obligation to pay or transmit money or property to the state or to any political subdivision" in violation of Cal. Gov't Code § 12651(a)(7).

366. By virtue of the acts described above, Defendants are "beneficiar[ies] of an inadvertently submission of a false claim, subsequently discovere[d] the falsity of the claim, and fail[ed] to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim" in violation of Cal. Gov't Code § 12651(a)(8).

367. The State of California, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

368. By reason of Defendants' acts, the State of California has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Cal. Gov't Code § 12651(a), the State of California is entitled to three times the amount of actual damages

plus a penalty of $5,500 to $11,000 per violation, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990.

COUNT XIII
COLORADO MEDICAID FALSE CLAIMS ACT
COLO. REV. STAT. §§ 25.5-4-305(1)(a), (b) & (f)

369. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

370. By virtue of the acts described above, Defendants "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Colo. Rev. Stat. § 25.5.-4-305(1)(a).

371. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Colo. Rev. Stat. § 25.5-4-305(1)(b).

372. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state in connection with the 'Colorado Medical Assistance Act', or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to the state in connection with the 'Colorado Medical Assistance Act'" in violation of Colo. Rev. Stat. § 25.5-4-305(1)(f).

373. The State of Colorado, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

374. By reason of Defendants' acts, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Colo. Rev. Stat. § 25.5-4-305(1), the State of Colorado is entitled to three times the amount of actual damages plus a civil penalty of not less than $5,500 and not more than $11,000 per violation; except that these upper and lower limits on liability shall automatically increase to equal the civil penalty allowed under the federal False Claims Act, 31 U.S.C. sec. 3729, et seq.

COUNT XIV
CONNECTICUT FALSE CLAIMS ACT
CONN. GEN. STAT. §§ 4-275(a)(1), (2), (7), (8) & (b)

375. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

376. By virtue of the acts described above, Defendants "[k]nowingly present[ed] or cause[d] to be presented, a false or fraudulent claim for payment or approval under a state-administered health or human services program" in violation of Conn. Gen. Stat. § 4-275(a)(1).

377. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim under a state-administered health or human services program" in violation of Conn. Gen. Stat. § 4-275(a)(2).

378. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state under a state-administered health or human services program" in violation of Conn. Gen. Stat. § 4-275(a)(7).

379. By virtue of the acts described above, Defendants "[k]nowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or

property to the state under a state-administered health or human services program" in violation of Conn. Gen. Stat. § 4-275(a)(8).

380. The State of Connecticut, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

381. By reason of Defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Conn. Gen. Stat. § 4-275(b), the State of Connecticut is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation, as adjusted by the federal Civil Penalties Inflation Adjustment Act of 1990.

COUNT XV
FLORIDA FALSE CLAIMS ACT
FLA. STAT. §§ 68.082(2)(a), (b) & (g)

382. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

383. By virtue of the acts described above, Defendants "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Fla. Stat. § 68.082(2)(a).

384. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Fla. Stat. § 68.082(2)(b).

385. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to an obligation to pay or

transmit money or property to the state, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to the state" in violation of Fla. Stat. § 68.082(2)(g).

386. The State of Florida, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

387. By reason of Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Fla. Stat. § 68.082(2), the State of Florida is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

COUNT XVI
GEORGIA STATE FALSE MEDICAID CLAIMS ACT
GA. CODE §§ 49-4-168.1(a)(1), (2) & (7)

388. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

389. By virtue of the acts described above, Defendants "[k]nowingly present[ed] or cause[d] to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval" in violation of Ga. Code § 49-4-168.1(a)(1).

390. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Ga. Code § 49-4-168.1(a)(2).

391. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to an obligation to pay or

transmit property or money to the Georgia Medicaid program, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit property or money to the Georgia Medicaid program" in violation of Ga. Code § 49-4-168.1(a)(7).

392. The State of Georgia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

393. By reason of Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Ga. Code § 49-4-168.1(a), the State of Georgia is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

COUNT XVII
ILLINOIS FALSE CLAIMS ACT
740 ILL. COMP. STAT. 175/3(a)(1)(A), (B) & (G)

394. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

395. By virtue of the acts described above, Defendants "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of 740 Ill. Comp. Stat. § 175/3(a)(1)(A).

396. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of 740 Ill. Comp. Stat. § 175/3(a)(1)(B).

397. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or

transmit money or property to the State, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to the State" in violation of 740 Ill. Comp. Stat. § 175/3(a)(1)(G).

398. The State of Illinois, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

399. By reason of Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to 740 Ill. Comp. Stat. § 175/3(a)(1), the State of Illinois is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

COUNT XVIII
INDIANA MEDICAID FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT
IND. CODE §§ 5-11-5.5-2(b)(1), (2), (6) & (8) (Before and on June 30, 2014)
IND. CODE §§ 5-11-5.7-2(a)(1), (2), (6) & (8) (After June 30, 2014)

400. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

401. By virtue of the acts described above, Defendants "[k]nowingly present[ed] or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Ind. Code §§ 5-11-5.7-2(a)(1) & (8) and Ind. Code §§ 5-11-5.5-2(b)(1) & (8) (before and on June 30, 2014).

402. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement that is material to a false or fraudulent claim" in violation of Ind. Code §§ 5-11-5.7-2(a)(2) & (8) and Ind. Code §§ 5-11-5.5-2(b)(2) & (8) (before and on June 30, 2014).

403. By virtue of the acts described above, Defendants "[k]knowingly: (A) ma[de], use[d], or cause[d] to be made or used, a false record or statement concerning an obligation to pay or transmit money or property to the state; or (B) conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to the state" in violation of Ind. Code §§ 5-11-5.7-2(a)(6) & (8) and Ind. Code §§ 5-11-5.5-2(b)(6) & (8) (before and on June 30, 2014).

404. The State of Indiana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

405. By reason of Defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Ind. Code § 5-11-5.7-2(a), the State of Indiana is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation, as adjusted by the federal Civil Penalties Inflation Adjustment Act of 1990.

COUNT XIX
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
LA. REV. STAT. §§ 46:438.3(A), (B) & (C) and 46:438.6

406. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

407. By virtue of the acts described above, Defendants "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim" in violation of La. Rev. Stat. § 46:438.3(A).

408. By virtue of the acts described above, Defendants "[k]nowingly engage[d] in misrepresentation or ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of La. Rev. Stat. § 46:438.3(B).

409. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the medical assistance programs, or [] knowingly conceal[ed], avoid[ed], or decrease[d] an obligation to pay or transmit money or property to the medical assistance programs" in violation of La. Rev. Stat. § 46:438.3(C).

410. The State of Louisiana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

411. By reason of Defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to La. Rev. Stat. § 46:438.6, the State of Louisiana is entitled to recover its actual damages, a civil fine not to exceed three times the amount of actual damages, plus a civil monetary penalty of $5,500 to $21,563 per violation.

COUNT XX
MARYLAND FALSE HEALTH CLAIMS ACT
MD. CODE, HEALTH-GENERAL §§ 2-602(a)(1), (2), (7), (8) & 2-602(b)(1)

412. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

413. By virtue of the acts described above, Defendants "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Md. Code, Health-General § 2-602(a)(1).

414. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Md. Code, Health-General § 2-602(a)(2).

415. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money or other property to the State" in violation of Md. Code, Health-General § 2-602(a)(7).

416. By virtue of the acts described above, Defendants "[k]nowingly conceal[ed], or knowingly and improperly avoid[ed] or decrease[d], an obligation to pay or transmit money or other property to the State" in violation of Md. Code, Health-General § 2-602(a)(8).

417. The State of Maryland, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

418. By reason of Defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Md. Code, Health-General § 2-602(b)(1), the State of Maryland is entitled to three times the amount of actual damages plus a penalty of up to $10,000 per violation.

COUNT XXI
MASSACHUSETTS FALSE CLAIMS LAW
MASS. LAWS. CH. 12 §§ 5B(a)(1), (2), (9) & (10)

419. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

420. By virtue of the acts described above, Defendants "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Mass. Laws. ch. 12 § 5B(a)(1).

421. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Mass. Laws. Ch. 12 § 5B(a)(2).

422. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to an obligation to pay or to transmit money or property to the commonwealth or a political subdivision thereof, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to the commonwealth or a political subdivision thereof" in violation of Mass. Laws. Ch. 12 § 5B(a)(9).

423. By virtue of the acts described above, Defendants are "beneficiar[ies] of an inadvertent submission of a false claim to the commonwealth or a political subdivision thereof, or [are] beneficiar[ies] of an overpayment from the commonwealth or a political subdivision thereof, and [] subsequently discover[ed] the falsity of the claim or the receipt or overpayment and fail[ed] to disclose the false claim or receipt of overpayment to the commonwealth or a political subdivision" in violation of Mass. Laws. Ch. 12 § 5B(a)(10).

424. The Commonwealth of Massachusetts, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

425. By reason of Defendants' acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Mass. Laws. Ch. 12 § 5B(a), the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

COUNT XXII
MICHIGAN MEDICAID FALSE CLAIMS ACT
MICH. COMP. LAWS §§ 400.607(1), (2), (3) & 400.612

426. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

427. By virtue of the acts described above, Defendants "ma[de] or present[ed] or cause[d] to be made or presented to an employee or officer of this state a claim under the social welfare act … upon or against the state, knowing the claim to be false" in violation of Mich. Comp. Laws § 400.607(1).

428. By virtue of the acts described above, Defendants "ma[de] or present[ed] or cause[d] to be made or presented a claim under the social welfare act … that he or she knows falsely represents that the goods or services for which the claim is made were medically necessary in accordance with professionally accepted standards" in violation of Mich. Comp. Laws § 400.607(2).

429. By virtue of the acts described above, Defendants "knowingly ma[de], use[d], or cause[d] to be made or used a false record or statement to conceal, avoid, or decrease an

obligation to pay or transmit money or property to the state pertaining to a claim under the social welfare act" in violation of Mich. Comp. Laws § 400.607(3).

430. The State of Michigan, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

431. By reason of Defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Mich. Comp. Laws § 400.612, the State of Michigan is entitled to three times the amount of actual damages plus a penalty of $5,500 to $10,000 per violation.

COUNT XXIII
NEVADA FALSE CLAIMS ACT
NEV. REV. STAT. §§ 357.040(1)(a), (b), (f), (g), (h) & 357.040(2)

432. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

433. By virtue of the acts described above, Defendants "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Nev. Rev. Stat. § 357.040(1)(a).

434. By virtue of the acts described above, Defendants "[k]nowingly ma[de] or use[d], or cause[d] to be made or used, a false record or statement that is material to a false or fraudulent claim" in violation of Nev. Rev. Stat.§ 357.040(1)(b).

435. By virtue of the acts described above, Defendants "[k]nowingly ma[de] or use[d], or cause[d] to be made or used, a false record or statement that is material to an obligation to pay

or transmit money or property to the State or a political subdivision" in violation of Nev. Rev. Stat.§ 357.040(1)(f).

436. By virtue of the acts described above, Defendants "[k]nowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to the State or a political subdivision" in violation of Nev. Rev. Stat.§ 357.040(1)(g).

437. By virtue of the acts described above, Defendants are "beneficiar[ies] of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fail[ed] to disclose the falsity to the State or political subdivision within a reasonable time" in violation of Nev. Rev. Stat.§ 357.040(1)(h).

438. The State of Nevada, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

439. By reason of Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Nev. Rev. Stat. § 357.040(2), the State of Nevada is entitled to three times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

COUNT XXIV
NORTH CAROLINA FALSE CLAIMS ACT
N.C. GEN. STAT. §§ 1-607(a)(1), (2) & (7)

440. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

441. By virtue of the acts described above, Defendants "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of N.C. Gen. Stat. § 1-607(a)(1).

442. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of N.C. Gen. Stat.§ 1-607(a)(2).

443. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to the State" in violation of N.C. Gen. Stat.§ 1-607(a)(7).

444. The State of North Carolina, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

445. By reason of Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to N.C. Gen. Stat. § 1-607(a), the State of North Carolina is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

COUNT XXV
RHODE ISLAND FALSE CLAIMS ACT
R.I. GEN. LAWS §§ 9-1.1-3(a)(1), (2) & (7)

446. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

447. By virtue of the acts described above, Defendants "[k]nowingly present[ed], or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of R.I. Gen. Laws § 9-1.1-3(a)(1).

448. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of R.I. Gen. Laws § 9-1.1-3(a)(2).

449. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to the state" in violation of R.I. Gen. Laws § 9-1.1-3(a)(7).

450. The State of Rhode Island, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

451. By reason of Defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to R.I. Gen. Laws § 9-1.1-3(a), the State of Rhode Island is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

COUNT XXVI
TENNESSEE MEDICAID FALSE CLAIMS ACT
TENN. CODE §§ 71-5-182(a)(1)(A), (B) & (D)

452. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

453. By virtue of the acts described above, Defendants "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval under the medicaid program" in violation of Tenn. Code § 71-5-182(a)(1)(A).

454. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Tenn. Code § 71-5-182(a)(1)(B).

455. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money, or property to the state, or knowingly conceal[ed], or knowingly and improperly, avoid[ed], or decrease[d] an obligation to pay or transmit money or property to the state, relative to the medicaid program" in violation of Tenn. Code § 71-5-182(a)(1)(D).

456. The State of Tennessee, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

457. By reason of Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Tenn. Code § 71-5-182(a)(1)(A), the State of Tennessee is entitled to three times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

COUNT XXVII
TEXAS MEDICAID FRAUD PREVENTION ACT
TEX. HUM. RES. CODE §§ 36.002(1), (12) & 36.052

458. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

459. By virtue of the acts described above, Defendants "[k]knowingly ma[de] or cause[d] to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized," in violation of Tex. Hum. Res. Code § 36.002(1).

460. By virtue of the acts described above, Defendants "[k]knowingly ma[de], use[d], or cause[d] the making or use of a false record of statement material to an obligation to pay or transmit money or property to this state under the Medicaid program, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to this state under the Medicaid program" in violation of Tex. Hum. Res. Code § 36.002(12).

461. The State of Texas, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

462. By reason of Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Tex. Hum. Res. Code § 36.052, the State of Texas is entitled to two times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

COUNT XXVIII
VIRGINIA FRAUD AGAINST TAXPAYERS ACT
VA CODE §§ 8.01-216.3(A)(1), (2) & (7)

463. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

464. By virtue of the acts described above, Defendants "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of VA Code § 8.01-216.3(A)(1).

465. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of VA Code § 8.01-216.3(A)(2).

466. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Commonwealth or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to the Commonwealth" in violation of VA Code § 8.01-216.3(A)(7).

467. The Commonwealth of Virginia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and conduct alleged herein.

468. By reason of Defendants' acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to VA Code § 8.01-216.3(A), the Commonwealth of Virginia is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

COUNT XXIX
CALIFORNIA INSURANCE FRAUDS PREVENTION ACT
CALIFORNIA INSURANCE CODE § 1871.7

469. Relator re-alleges and incorporates each and every allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

470. Defendants did and/or aided, abetted, solicited, and/or conspired with persons to do the following:

(a) Knowingly presented or caused to be presented false or fraudulent claims for the payment of a loss or injury under a contract of insurance (Cal. Penal Code § 550(a)(1));

(b) Knowingly prepared, made, and/or subscribed any writing, with the intent to present or use it, and/or to allow it to be presented, in support of any false or fraudulent claims (Cal. Penal Code § 550(a)(5)); and

(c) Knowingly made, and/or caused to be made false and/or fraudulent claims for payment of a health care benefit (Cal. Penal Code § 550(a)(6)).

471. As more specifically alleged herein, Defendants did and/or knowingly assisted and/or conspired with persons to do the following:

(a) Presented and/or caused to be presented written or oral statements as part of, or in support of a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false and/or misleading information concerning any material facts (Cal. Penal Code § 550(b)(1));

(b) Prepared and/or made written and/or oral statements intended to be presented to any insurer or any insurance claimant in connection with, and/or in support of claims and/or payments and/or other benefits pursuant to an insurance policy, knowing that the statements contained false and/or misleading information concerning material facts (Cal. Penal Code § 550(b)(2)); and

(c) Concealed and/or knowingly failed to disclose the occurrence of, an event that affects any person's initial and/or continued right and/or entitlement to any insurance benefit and/or

payment, and/or the amount of any benefit and/or payment to which the person is entitled (Cal. Penal Code § 550(b)(3)).

472. Defendants' fraudulent scheme represented the inducement of healthcare benefits through a pattern and practice of fraudulent conduct and constitutes false claims within the meaning of Cal. Ins. Code § 1871.7 and Cal. Penal Code § 550(a) and (b).

X. PRAYER FOR RELIEF

473. WHEREFORE, Relators, on behalf of the United States and the Plaintiff States, demand that judgment be entered in their favor and against Defendants for the maximum amount of damages and such other relief as the Court may deem appropriate on each Count. With respect to the Federal FCA, this includes three times the amount of damages to the United States plus civil penalties for each false claim, and any other recoveries or relief provided for under law. This request also includes, with respect to the Plaintiff States' false claims act statutes and the IFPA, the maximum damages, the maximum fines or penalties, and any other recoveries or relief provided for or permitted by those state statutes.

474. Further, Relators request that they receive the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the United States and the Plaintiff States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs. Relators request that their award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities who are not parties to this action.

XI. JURY TRIAL DEMANDED

A jury trial is demanded in this case.

August 7, 2020

Respectfully submitted,

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